WORLD MEDICAL JOURNAL

VOL. 50 No. 2, JUNE 2004

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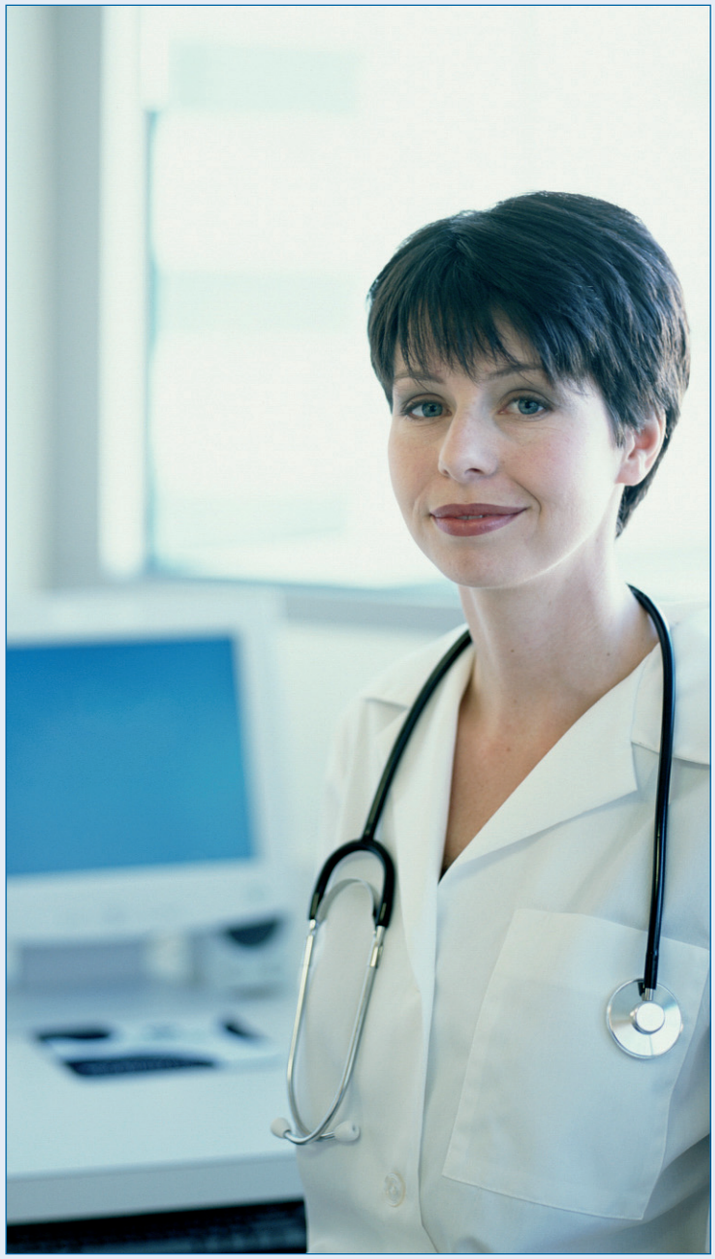

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Deutscher Ärzte-Verlag GmbH, Dieselstr. 2, P. O. Box 40 02 65, 50832 Köln/ Germany, Phone (0 22 34) 70 11-0, Fax (0 22 34) 70 11-2 55, Postal Cheque Account: Köln 192 50-506, Bank: Commerzbank Köln No. 1 500 057, Deutsche Apotheker- und Ärztebank, 50670 Köln, No. 015 13330.
At present rate-card No. 3 a is valid.

The magazine is published quarterly.

Subscriptions will be accepted by Deutscher Ärzte-Verlag or the World Medical Association.

Subscription fee € 22,80 per annum (incl. 7 % MwSt.). For members of the World Medical Association and for Associate members the subscription fee is settled by the membership or associate payment. Details of Associate Membership may be found at the World Medical Association website www.wma.net

Printed by
Deutscher Ärzte-Verlag
Köln — Germany

ISSN: 0049-8122

Editorial

Health professionals and society

The month of May has seen the 167th meeting of the WMA Council, the first global meeting of the World Health Professions Alliance, the launch of the World Health Organisation's 2004 Report and the meeting of the World Health Assembly (WHA). In this issue there are reports of the outcomes of some of these meetings and the key decisions taken by these bodies. From these it is clear that major health issues confront all parts of the world. They vary from the crises facing countries in Sub-Saharan Africa and appeals to support the urgent action needed to reduce the potential 6 million deaths from AIDS in the next few years – not to mention the global actions on tuberculosis and malaria prevention and control, to calls to take action to contain the increase of AIDS in Eastern Europe and to the links between poverty and health. These were addressed by all these groups.

Amongst the topics addressed by the WHA was also that of migration of health professional workers from developing countries to developed countries. This has a special significance. Seen against the huge need for physicians, nurses, pharmacists and all health professionals to deliver the care needed by those affected within the disease groups mentioned above, and the other problems of ensuring equitable provision of health care in all countries, this calls for particular reflection and action. In so doing, two other problems need to be addressed.

The fundamental changes in society in general, linked to the major advances in medical science, increased access to knowledge associated with the huge developments in IT and the consequent increased expectations of those in need of healthcare, have had a substantial impact on the health professions and professional practice. These are reflected in challenges to the perceptions of the role of professionals in society, and the need to critically analyse and often modify the role of individual professionals from their traditional roles. For some health professionals this may mean increasingly restricting their activities from broad areas traditionally considered to be within their field of activity, to a narrower, more specialised area of activity. In other cases, it may call for the development of new skills with an enhanced role and new responsibilities, For most, it requires coordination through teamwork with relevant health professonals. None of these changes is limited to any one profession. For all, there is some degree to which they have to reassess their relationship with society.

At the same time, society needs to consider what it seeks from the health professions.

One consequence of the many scientific advances and developments in health care has been the increasing recognition of the value of and necessity for teamwork with other professionals. This calls for a real mutual recognition of each other's skills and competencies, not always an easy process, but one which is clearly essential if the fundamental values of professionalism and professional practice, notably in ensuring quality of care, are to be recognised and accepted by society as the basis for the relationship with the professions.

For physicians, the societal changes are particularly important. While often the relationship between an individual physician and the patient is highly regarded, in today's changing world a more critical assessment of the professional is developing, not infrequently reflected in a critical attitude, challenging the role and functioning of the profession. At a time when there is a shortage of physicians in many parts of the world (with the associated problem of recruitment from developing to developed countries), physicians are under greater pressure than ever before. These pressures not only reflect increased workload, but the demands of a globalised world, in which market pressures and competition are promoting continuing administrative and managerial change, and demanding higher and higher quality of care at a lower cost.

One element of professionalism is the delivery of high-quality services. In medicine this requires not only the traditional devotion to the best interests of patients and a high standard

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of professional services, but also the maintenance and enhancing of the knowledge, skills and attitudes necessary to achieve this. In a climate of increased pressures and demands on work and work practices from both patients and health care administrations, the allocation of dedicated time for continuing professional development becomes more and more difficult.

This pressure is increased by continuing problems of limited resources, and demands for more working time to be devoted to "hands on" delivery of services. With increasing sophistication of medical technology resulting from important scientific advances, and the resultant raising of public expectations, the demands for healthcare resources are constantly rising. But in the market economies of today, in both public and private sectors this leads to constant pressures for cost containment. It is therefore imperative that time as well as resources be made available to individual practitioners so that their knowledge, skills and attitudes can be maintained and enhanced through Continuing Professional Development (CPD), and that they can provide the highest standards of medical care within the resources available to them. The WMA Council has endorsed a proposed resolution on Global Standards for Quality Improvement of Medical Education which will go to the General Assembly for adoption. The third document to which this resolution refers concerns Quality Improvement and Continuing Professional Development (CPD), emphasising the importance of this in meeting the challenges of health needs. What has been said in this paragraph is, as set out above, relevant to all health professionals.

Continuing education and maintenance of skills is not limited to any one profession. For example, the initiatives for the control of AIDS and provision of AVRs and the measures to "Roll Back Malaria" all require appropriate education of many health professionals in new approaches, teamwork and organisation, communication techniques, etc. This is, of course, but one part of the resources needed to carry out these programmes.

One question has to be addressed. How far does "society" recognise even the few examples of health professionals' problems referred to above, major disease threats and changing disease patterns, manpower, redeployment of skills, continuing professional developmental needs and overall health resources?

When governments support global policies, as for example the Diet, Physical Activity and Health Initiative adopted at the WHA, do they intend to simply add these to the burdens of health care demands of health professionals, or will they state honestly to their citizens that this not only requires more personal responsibility by individuals for their own health, but also redeployment of current healthcare resources, the recruiting and training of new professionals and the retraining of some existing professionals? Of course the policy recognises the substantial burden of public education needed, but this of itself requires specialised training.

This is, of course, relevant to the fundamental problem of the relationship of health professionals to society.

For most of the past century and a half, the relationship between physicians, individuals and society as a whole has, on the part of physicians, been substantially based on a paternalistic humanistic approach. Increasingly, in the later years of the 20th century, both the profession and society began to recognise the need for some change. Some of the developments triggering this need are set out above. Change however can no longer be treated as a gradual process. Real dialogue between the profession and society, at individual, local and national levels, is imperative, at as clear understanding of this relationship is fundamental to the practice of medicine. Whilst technology may to an increasing extent intrude on the more holistic approach to medical care, the human race is not a uniform automated group in which the functioning of each individual member is identical, and repair when needed can be provided through a simple adjustment or replacement. To meet the needs of society and achieve the goals set out in the WHO definition of health, requires more than technology. It requires the devotion and professional knowledge, skills and attitudes of physicians, the necessary technical resources and the cooperation of individuals, both in responsibility for their own health and in an equal partnership with the professional(s) to meet the health requirements at any one time.

This all constitutes a challenge which calls for analysis, leadership and dialogue both at national level and between individual physicians and members of the public, to identify both those traditional qualities of professional practice which need to be preserved and any new ones necessary to ensure a positive partnership between professionals and society contributing to ensuring successful health care services and contented health professionals and patients.

Alan Rowe

"WHO and WHPA need each other"

With these words Dr. Lee Jong-wook Director-General of the World Health Organization, ended his address at the concluding session of the first global conference of the World Health Professions Alliance on "Training for Better Health". Dr. Lee's speech to this assembly of leaders of the medical, nursing and pharmaceutical professions set out below, highlights the importance of their role in turning health ideas into realities and confronting the huge health problems facing the world today.

"I am very happy to be with you here today. "Making it happen" is one of our current commitments, and you are the people who do just that. It is the work of doctors, nurses, pharmacists and other health professionals that turns health ideas into realities, and strategies into achievements.

Our current efforts include providing treatment, care and prevention services to control AIDS, TB and malaria; large-scale immunization campaigns to eradicate polio; and promoting healthy lifestyles. These and our other programme areas give some idea of objectives we are working for and they provide the necessary framework for our efforts. Their attainment, however, depends to a very large extent on the work you do with the users of the health system.

In addition, we have to respond to emergencies. SARS and Avian Influenza continue to be a major concern particularly in our Western Pacific Region. Their control has depended to a very significant extent on the efforts of people in your three professions.

Armed conflict and natural disasters also continue to impose extreme and unforeseeable demands, particularly on doctors and nurses. They can occur in any part of the world but are particularly severe at present in parts of our Eastern Mediterranean and African regions. Courage and tenacity will continue to be key requirements for health leadership in the future, not only in disaster areas but in the many places where health work is under-funded, under-equipped and under-staffed.

Just as health authorities depend on your professions to put policy into practice, health workers need good policies to work with. The current shortages of human resources, especially in developing countries, reflect the need for an enormous effort at rethinking and rebuilding health services. This is a unifying theme in all our acitivities at present.

One of our most important current initiatives is to scale up access to antiretroviral therapy for people living with HIV/AIDS. In December last year, on World AIDS Day, WHO launched the strategy to accelerate access to antiretroviral treatment. The initial objective is to get three million people in developing countries on to treatment by the end of 2005. We are working with the health services in countries to achieve this, following a double imperative: universal access to treatment by the earliest possible date, and ever more effective approaches to prevention.

The Millennium Development target for HIV/AIDS is to halt the spread of HIV and begin its reverse by 2015. The ratio of treated cases to infections prevented is not yet known but, if for each person receiving treatment there were just one new HIV infection averted, the “3 by 5” initiative will significantly speed up the achievement of this target.

Procurement and distribution of the drugs needed is involving excellent and innovative co-operation with the pharmaceutical professions. A hundred thousand health providers and community treatment supporters will be needed to staff the necessary delivery systems. They will need to be trained in antiretroviral therapy in accordance with national standards. It is the medical, nursing and pharmaceutical professions above all that will meet this training need.

With your leadership, these efforts can mark the beginning of new strength and coherence in national health systems, and start the trend towards solving staff shortage problems. The work of the International Council of Nurses in mobilizing skilled health workers in primary health care is already making a very valuable contribution.

Our long-term disease control programmes include polio eradication. Here the key to success will be tenacity, both in our colleagues running the immunisation campaigns and maintaining surveillance, and in our donors. We are on the verge of eradication, with just twenty-two cases to date this year in all of Afghanistan, Egypt, India and Pakistan.

On the other hand, we have had setbacks in West and Central Africa, with an explosive outbreak that has paralysed over 500 children. The leaders in these areas have now restarted with massive immunisation campaigns and strengthening routine services as an emergency measure. In these last stages of the campaign, where so much can be either lost or gained, high levels of commitment are needed, and the ability to cope with practical difficulties as they arise. Here leadership, especially at the local level, is the key to success, as we have seen in every country and region where eradication has been achieved.

Equally important is the work of health promotion. This is particularly needed for the early prevention of cancer, cardiovascular diseases, diabetes and other chronic conditions. Sixty per cent of the deaths that occur annually in the world are from non-communicable diseases.

The Framework Convention on Tobacco Control, adopted a year ago, was a great achievement. The efforts of the pharmacists and other associations played a very important part in the success of the negotiations. The Convention has now been signed by 108 countries plus the European Union, and ratified by 12. Your efforts are still needed in the countries that have not yet ratified it, to help speed the process on its way. Once ratified by 40 countries, the Convention will come into force and provide valuable support for tobacco legislation and policy. It will help to protect the public – especially children and adolescents – from one of today’s most serious and most unnecessary health hazards.

As requested by the World Health Assembly in 2002, we have prepared the Global Strategy on Diet, Physical Activity and Health, for consideration and adoption next week. When the Strategy is adopted, we will work with Member States to implement it according to their particular needs.

I attended the World Conference on Health Promotion and Health Education in Melbourne last month, and was encouraged to see the high level of support from health professionals for healthy lifestyles. Community involvement is a central principle in the health-for-all approach and now, more than ever, it can make a great contribution to reducing some of the current major causes of death and disability. It is the health professions that provide the guidance for this broader effort.

The theme of World Health Day in April this year was Road Safety. It drew attention to the 1.2 million deaths and up to 50 million injuries that occur on the roads each year. The Government of France hosted the global World Health Day event in Paris, with eloquent support from President Chirac. The highlight of the event was the launch of the WHO and World Bank World report on road traffic injury prevention.

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As an immediate follow-up to this successful World Health Day, the UN General Assembly met in plenary session on the global road safety crisis. They adopted a resolution inviting WHO to co-ordinate the UN road safety effort. Your support in promoting the many practices that can reduce road traffic accidents will be much needed.

I could go on at length, but I'd prefer to leave as much time as possible for discussion. So let me conclude by saying: our organizations need each other. Your work is much more highly appreciated than you are probably aware of most of the time. I'm very glad we have the opportunity of this Symposium to co-ordinate our efforts."

World Health Professions Alliance holds its first global meeting

At a historic meeting in Geneva on 15-16 May, the World Health Professions Alliance held its first global conference under the title "Teaming up for health" The meeting brought together for the first time at global level leaders representing member organisations of the International Council of Nurses (ICN), the International Pharmaceutical Federation (FIP) and the World Medical Association (WMA). Sixty-five countries were represented by more than 250 people, including observers from a number of other health professions and non-governmental agencies.

From the enthusiasm in the hall it was clear that the organisers had gone a long way towards the objective of motivating health professionals and their organisations to work together at local, national and international levels to respond to the huge health challenges facing the world today.

Speakers were drawn from the health professions, policy makers, patients' disease group organisations and supranational bodies, both intergovernmental and non-governmental.

From the opening remarks of the three professions, it was clear that few doubted that a united voice from the professionals delivering health care could be more effective when dealing with the huge health problems facing the world today, which require governments to engage in positive actions for humanity at large, not only for their own communities.

Those present demonstrated this in a positive way, responding to the clear statement of reality in which Stephen Lewis, UN Special Envoy for HIV/AIDS in Africa, underlined the immediacy of the crisis in Africa, and the grave risk of this extending in a short time to the Indian sub-continent and to China. The certain death of six million people in Africa from HIV/AIDS in the next few years, and the increasing number of orphans, were illustrations which could not be ignored. The Conference adopted unanimously the following resolution:

"Recognising that

- *the current HIV/AIDS pandemic presents an extraordinary human, human rights and humanitarian crisis;*
- *especially women and children are affected;*
- *focused prevention programmes can significantly reduce new infections;*
- *treatment options allow HIV positive persons to lead a quality life;*
- *without the appropriate prevention and treatment this crisis will worsen to a level where some countries' populations may be decimated and their futures destroyed; and*

that countries at the heart of the HIV/AIDS pandemic, provided that they are supported with the necessary financial and human resources, can rise to the challenge.

Therefore we, as leaders of the medical, nursing and pharmacy professions, call on all governments, intergovernmental agencies and health professionals to recognise the scale of the tragedy, to stop procrastinating and to commit immediately, the necessary funds and resources against HIV/AIDS.

As health professional leaders we give our full commitment to this cause and call on all physicians, nurses and pharmacists to act as strong advocates and social leaders in the war against HIV/AIDS."

In a final address to the meeting, the Director-General of the World Health Organization (WHO), Dr. Lee Jong-wook, acknowledged and appreciated the resolution set out above, which responded to the concerns expressed clearly in the World Health Report 2004 and to which he had referred in his presentation.

Note:

The World Health Professions Alliance brings together medicine, nursing and pharmacy through their representative international organisations, the International Council of Nurses (ICN), the International Pharmaceutical Federation (FIP) and the World Medical Association (WMA), and represents more than 20 million health professionals worldwide.

The WHPA website is: www.whpa.org
e-mail: info@whpa.org

During the WHPA meeting an informal poll of participants' opinion revealed that over the next five years they expected heart disease, obesity and cancer to be top priorities in both developing and developed countries. They also identified dietary change, unequal access to information, and trade policies as top trends affecting these health challenges. On the other hand, out of a list of 16 health challenges, HIV/AIDS was rated lower at 10 & 11, suggesting that fighting the pandemic is still not regarded as an urgent problem by some health professionals despite unanimous support by participants in the resolution on this subject. Dr. Delon Human commented that this choice suggested that "health professionals were underlining the importance of the lifestyle changes that the world is witnessing – an increasingly sedentary life and unhealthy eating".

Medical Ethics and Human Rights

The Relationship Between Physicians and Commercial Entities

MALKE BOROW, Adv.

Israel Medical Association

An overview based on a paper presented to the WMA Council

There is general acceptance that the relationship between physicians and industry is complex, and one that has been subject to increasing scrutiny, in particular in the past decade.

Such scrutiny has been substantially focused upon the relationship between the pharmaceutical industry and practising physicians. Potential problems can arise when physicians are visited by representatives of the pharmaceutical industry who, by offering gifts such as equipment, travel expenses or hospitality at medical or scientific meetings, offer the possibility of influencing the prescribing of individual physicians.

While there are substantial differences in practices from one country to another, the direct relationship between the pharmaceutical or other sectors of the technical health care industry and individual physicians who prescribe or use their products is a real phenomenon that can raise serious ethical issues.

US papers suggest that an estimated 11 billion dollars is spent by pharmaceutical companies each year in promotion and marketing, of which 5 billion goes to sales representatives. One recent US report put the figure as high as 9 billion, with some top firms spending more than 1 billion on their sales representatives each year [1]), including an outlay of approximately $8000-13,000 per physician. [2]

Another USA study states that physicians meet with industry representatives about 4 times a month, a phenomenon that begins as early as residency, and although the frequency with which physicians receive gifts and samples decreases as they enter practice, the frequency of receiving honoraria, conference travel and research funding increases. Both residents and established physicians frequently use promotional material. [2]

However, it can be argued that contact between physicians and the pharmaceutical industry is necessary. Industry representatives are a convenient and efficient, if not always the most reliable, way for physicians to learn about new medications. In addition, there is little doubt that without the support of industry, many scientific and medical developments would not be possible For example, 60% of biomedical research and development in the USA is privately funded. [3] Governments and academic institutions often lack the resources to provide similar support for research.

The increasingly aggressive advertising tactics of the pharmaceutical industry, and the necessity that physicians remove themselves from any real or suggested conflict of interest that could potentially affect the health of patients, requires that limitations and guidelines be established and adhered to.

Because conferences, even more than other issues, are so often international, and involve physicians from various countries, and because sponsorship for conferences often comes from pharmaceutical companies located outside the hosting country, there is a need for formal guidance at the global level, analogous to similar instruments issued by the WMA for the benefit of both practising physicians and society as a whole. There are already a number of sources of advice in this area such as guidelines from WHO, national medical associations and the pharmaceutical industry itself, but there is clearly a case for one set of principles to be established for the medical profession globally.

Why such global guidelines from the medical profession are needed

As in all matters ethical, reasonable men (and women) can differ. In such cases, where there are legitimate interests on both sides and the boundaries of what is appropriate are not always obvious, there is a need for clear guidelines.

While it can be argued that the resources provided by commercial entities for research, continuing medical education, etc. are indispensable, the funding of such activities, not to mention the offering of gifts to doctors by companies whose interests are not purely altruistic in nature, pose ethical problems.

The linking of gifts, hospitality or other perks directly to prescribing practices is clearly indefensible and unethical. However, there is evidence that, even where there is no direct link, gifts do create a feeling of social obligation that may subtly influence prescribing behavior. [4] On the most basic level, gifts make one feel good, and these feelings may be subtly transferred to the sales representative or company's product. [5] Even "gifts" such as funding for conferences may influence a doctor's choice of medical conferences, and thus, the information to which he or she is exposed. [5]

Ultimately, the cost of any such activity by a commercial enterprise in the health field is borne either directly or indirectly by the patients as consumers of the enterprises' products. These patients/consumers may not be aware that their physicians are receiving these benefits.

The funding of such benefits to physicians also damages the image of the profession. [4] The position paper of the American College of Physicians-American Society of Internal Medicine (ACP-ASIM) on physician-industry relations states: "A perception that a physician is dispensing medical advice on the basis of commercial influence

is likely to undermine a patient's trust, not only in the physician's competence but also in the physician's pledge to put patients' welfare ahead of self-interest." [6] Even if there is no direct effect on a physician's behavior, the fact that this trust is damaged is reason enough to be wary. In fact, limits on the acceptance of gifts to avoid the appearance of impropriety are prevalent in other parts of society, such as holders of public office in the federal government and many private companies. [5]

Studies have shown that the existence of guidelines has a tangible effect on physicians' attitudes and behaviour towards pharmaceutical representatives. The difference is noticeable, beginning in the training period. In a random sample of 378 residents from 14 US family medicine training programs, half of which had written policies in place that restricted residents' behaviour regarding pharmaceutical representatives, and half that had no such policies, there was a marked difference in attitudes. Twice as many residents of "non-restricted" programs felt that the information received from pharmaceutical representatives was of good quality, that social activities sponsored by them were beneficial or that contact with pharmaceutical representatives was generally beneficial to the residency experience. In addition, more than twice as many residents in non-restricted programs felt that meals, gifts or social outings funded by industry were appropriate. [7]

This difference in attitude continues even after the training period. In a survey of Canadian physicians, some of whom had been exposed to such policies, and some of whom had not, it was found that residents who had more contact with pharmaceutical representatives during training were more likely to perceive the information provided by such representatives as beneficial, and to have greater contact with them in later years. [8]

Existing guidelines

Codes of conduct regarding the relationship between physicians and the pharmaceutical industry tend to be written by doctors, i.e. medical associations, institutions or regulatory authorities, or by the pharmaceutical industry itself.

Codes developed by industry are generally voluntary, although they are often reinforced by complaints procedures with possible sanctions [9]. Such codes, although discouraging egregious conduct such as direct cash payments to doctors, often do little more than endorse existing modes of behavior. [10] For example, under the new voluntary code of PhRMA (a group of pharmaceutical industry representatives), if a company flies 300 doctors to a golf resort, all expenses paid, and educates them about the company's latest drug so the doctors may then be "paid spokesmen" for the drug, this would be entirely legitimate. [10, 11]

Many countries with major pharmaceutical industries such as Britain, Australia and the United States have national codes that usually prohibit companies from giving doctors incentives to prescribe their products (9). In addition, the relevant European Union Directives on Advertising (92/28/EEC & 84/450/EEC) also restrict the nature and value of such "promotional activity". For those countries that lack national codes, there are two major sets of international guidelines: the WHO's Criteria for Medicinal Drug Promotion and the Code of Pharmaceutical Marketing Practice, put out by the International Federation of Pharmaceutical Manufacturers Associations. [9]

While the focus of guidelines put out by the pharmaceutical industry is generally on marketing, codes put out by medical professional organizations tend to focus more on commercially funded research. There are also guidelines written by organizations such as the American Academy of Pharmaceutical Physicians and the Royal College of Physicians Faculty of Pharmaceutical Medicine. [9]

It must be noted that even where guidelines exist, in some countries physicians are often unaware of them [2]. For instance, in a US study only 23-50% of medical residents knew of the existence of guidelines and only 62% of practising physicians were aware of at least one guideline [12]. In addition, while awareness of guidelines did not necessarily elicit compliance, enrolment in a residency program that mandated compliance with the guidelines, did. [2]

National regulating patterns for physicians

The range of options for regulating the physician-industry relationship varies from country to country:

Denmark – The Danish Medical Association and the Pharmaceutical Industry (LIP) have signed an agreement on Cooperation between the Profession and the Industry, which is substantially concerned with scientific and medical meetings. Commenting that close cooperation between the two bodies "is necessary to develop new and better pharmaceutical therapy and ensure that existing therapies are used in the best possible way in patient treatment", both parties find that this cooperation should "be conducted in such a manner that it does not include any aspect of pressure between the parties and that the parties are independent of each other". It incorporates conditions concerning transparency and strict accountability, including requiring the company organising or co-organizing medical or scientific meetings to notify the National Board of Drug Advertising (NMI) – a statutory body – with the details of the arrangement. The NMI and the DMA (Medical Ethics Board) are respectively responsible for dealing with violations by the profession or the industry.

France – The French Medical Association has tightened its rulings on issues relating to gifts and conferences. For instance, a doctor should not accept gifts in cash or otherwise, unless they are small gifts of nominal value (not exceeding 30 Euro). Contributions to a doctor's attendance at a scientific conference are authorised if they are reasonable, and/or if the selection of a remote (i.e., costly) location is justified. [13]

Spain – A body representing the Spanish pharmaceutical industry issued a code of practice in 2002 stating that drug companies may offer medically related gifts worth up to 19 Euro. Expenses for meetings may not include social or cultural events or expenses of spouses. [13]

India – The practice of offering gifts to doctors, including foreign trips and outright cash gifts, is widespread in India, especially in "big money" areas such as cardiology.

The Medical Council of India, in its Code of Ethics released March 2002, does not relate to doctors accepting gifts or cash from drug companies. [13]

Israel – Israel has historically had selected guidelines written by the pharmaceutical industry, the government, the health funds and the medical profession. Over the past year, several events occurred that portend changes in the current status. The Israeli Parliament has begun deliberations on a proposed law that seeks to codify the relationship between physicians and the pharmaceutical industry. The Israel Medical Association (IMA) opposes this law, feeling that legislation is not the proper place for such guidelines, that the guidelines are too far-reaching and that the profession is the appropriate body to draft such guidelines. Concurrently, the IMA has released a set of updated, encompassing guidelines. It is also in the process of finalizing an agreement between the IMA, the pharmaceutical industry and the providers and insurers of health care, that would set guidelines acceptable to all parties and define to whom each party would be accountable. It is felt that such a formal agreement would have a greater effect than guidelines put out by individual parties.

Singapore – The Singapore Medical Association, in conjunction with the Singapore Association of Pharmaceutical Industries, released in August 2000 a detailed statement regarding the relationship between the medical profession and the pharmaceutical industry. The statement begins by recognising both groups as partners in health care delivery, but adds that strict rules for professional conduct between the two parties is necessary in order to prevent abuses. The physician must always be known by his or her patients to be impartial and not influenced by commercial gain when determining the appropriate treatment for individual patients. Therefore, physicians must ensure that their professional judgement is in no way clouded by gifts, hospitality or the like. Educational conferences must be first and foremost scientific and educational in nature; the level of hospitality must be secondary, and should not exceed that which physicians might normally pay for themselves. In addition, making hospitality or other benefits conditional on prescribing performance is prohibited. Any form of sponsorship of such events should be clearly disclosed to participants.

In accordance with the principles of good practice, scientific research carried out in conjunction with the pharmaceutical industry must be properly planned and executed, including approval by an ethics committee, and subject to specific conditions detailed in the statement.

Gifts and other promotional items given to physicians by drug companies should primarily benefit patients, be modest in value and be related to the physician's work. Cash payments as incentives for prescribing are unacceptable. Medical books may be given to physicians if they serve a genuine educational function.

Travel expenses to overseas medical conferences may be offered if the subject of the conference is directly related to the doctor's work. They should not be offered if they are conditional on the doctor's past or present prescribing habits or upon any obligation to promote a specific product, nor should they include expenses for additional days or for accompanying persons such as spouses. Reasonable honoraria and reimbursement of travel and out-of-pocket expenses for speakers are acceptable.

Physicians invited to lecture at industry-sponsored events are also subject to strict guidelines regarding the content and presentation of their talks. Every effort must be made to ensure that the talk is professionally sound, objective and not influenced by the sponsoring company. For instance, the content of the lecture should be reviewed by others, and any conflict of interest must be declared. [14]

Australia – Australia has ethical guidelines prepared by the AMA, by the Royal Australasian College of Physicians and by the pharmaceutical industry, represented by APMA, now known as Medicines Australia – a body representing over 50 companies (about 95% of the prescription drug market). The latter's code, although monitored predominantly by industry, involves the Therapeutic Goods Administration, the Australian Medical Association and the Royal College, in its complaints body and monitoring and review process. [15]

The code of the pharmaceutical industry, in particular, is quite detailed and comes with guidelines regarding each section. Under reforms to the pharmaceutical industry's code enacted in 2002, all non-essential hospitality is prohibited. Thus when sending doctors to conferences, the code provides that travel may be subsidised provided the meeting is directly related to the doctor's area of expertise. In addition, travel within Australia should be economy class, abroad it may be economy or business, a reasonable level of accommodation may be offered plus travel costs, but the payment of expenses for family members is prohibited.

The Code states that hospitality must be secondary to the educational purpose of the meeting. The guidelines expand upon this in great detail, even going so far as to list types of acceptable foods. "An appropriate level of hospitality would be what is expected in a normal business meeting. For example, open sandwiches, rolls and quiches would be appropriate for lunch. Lavish hospitality such as lobster and caviar would not be appropriate."[16]

The Australian Medical Association guidelines state that any professional interaction between doctors and industry should be primarily for the advancement of the health of patients, rather than for any personal self-interest. Specifically, the guidelines state, *inter alia*, that before becoming involved in any research project sponsored by industry, a physician must satisfy himself that the project has genuine merit, is ethically defensible, socially responsible and scientifically valid. The project must also be reviewed by an appropriate review body. All moneys should be held in trust and subject to audit and review by the ethics committee. CME activities must address the educational needs of the targeted medical audience, not just the promotional needs of the contributing pharmaceutical company. The programme for such activities may acknowledge, but not excessively promote, the company's product.

Doctors may not accept personal gifts from the pharmaceutical industry but may accept

educational materials appropriate to their area of practice.

The Code of the Royal Australasian College of Physicians is quite similar, but goes into greater detail; e.g., regarding gifts it adds that payment for dinners, entertainment or expenses associated with daily living may not be accepted and gives great detail regarding industry-sponsored travel and attendance at meetings.

United States – In 1990, following a decade of lavish gifts, cash and trips to luxury resorts offered to physicians by the pharmaceutical industry, both the AMA and the American College of Physicians released guidelines to prevent inappropriate gift giving, later included in the AMA's code of medical ethics. These guidelines were adopted by the industry, represented by PhRMA. The AMA supplemented their guidelines with a series of questions and answers designed to clarify the issues. Gifts of minimal value (less than $100) and related to the physician's work (such as pens and notepads) or intended for the patient's benefit (such as medical textbooks) are permitted under the guidelines. Cash may not be accepted, and no gifts may be accepted if there are strings attached. Pharmaceutical companies may underwrite CME conferences that serve a genuine educational function and are not lavish in their attending hospitality; disclosure of financial support should be made. Despite the detailed guidelines of the code, an AMA-sponsored survey in 2000 indicated that up to half of American physicians were unfamiliar with it, and many routinely ignore it. [17]

As mentioned above, the pharmaceutical industry, represented by PhRMA, has also issued guidelines regarding interactions between healthcare professionals and the pharmaceutical industry, the most recent of which took effect in July 2002. Their new code makes it clear that interactions between the two groups must be intended to benefit patients and enhance the practice of medicine. The code permits professional presentations by industry that provide valuable scientific and educational benefits (a term that can, of course, be loosely applied) and assumes that such presentations occur at venues conducive to providing scientific or educational information. Modest meals, but no other entertainment, may accompany these presentations. The code also specifies that gifts worth less than $100 may be offered to doctors if they are primarily for the benefit of patients. Consulting arrangements with physicians are allowed if they serve a legitimate need. The PhRMA code, like the AMA code, also contains FAQs. [11]

In addition to the voluntary codes established by the AMA and PhRMA, the Department of Health and Human Services' Office of Inspector General issued in 2002 a 44-page document dealing with the making and marketing of pharmaceutical products. Unlike the AMA and PhRMA codes which are totally voluntary and which the OIG refers to as a "good starting point", the OIG guidelines, although apparently voluntary, can prompt government investigations if not adhered to. [18]

United Kingdom – In the UK, the prevailing Code of Practice is that of the Association of the British Pharmaceutical Industry (ABPI), the most recent version of which was released in 2001 in consultation with the British Medical Association. The ABPI code states that gifts from companies must cost less than 6 pounds (about 9 US dollars), and be relevant to the doctor's work. The accompanying text explains that "pens, diaries and surgical gloves are acceptable, while table mats, plant seeds and music CD's are not."[19] The ABPI code also contains guidelines on research.

Self-policing of the ABPI code seems to work. Complaints are reviewed by the Prescription Medicines Code of Practice Authority, which is independent of the ABPI and comprises 12 members from pharmaceutical companies, six independent members and a chairman. [9]

World Health Organization – WHO released in 1999 a preliminary version of guidelines on interaction with commercial enterprises. Although the guidelines deal with interactions between WHO as an organisation, and commercial enterprises of various sorts (as such they cover a broader base than do guidelines relating to the typical individual doctor and the pharmaceutical industry), there is still much to be gleaned from these guidelines. It should be noted, however, that the WHO guidelines are stricter than the typical doctor-pharmaceutical industry guidelines. For instance, WHO receptions and similar functions may not be paid for at all by commercial enterprises.

In companies where codes or other guidelines exist, physicians may be subject to sanctions for failing to adhere to such guidelines. For example, in Germany, thousands of doctors in 100 public hospitals were accused of accepting money and gifts from SmithKline Beecham, an international drug firm, and were subsequently investigated. [20] In the Netherlands, also, the marketing code has resulted in legal cases against pharmaceutical companies and individual doctors in matters of giving and receiving excess hospitality and other drug promotion "bonuses."[13, 21] Italy and France have also seen investigations of cases where doctors were given computers, trips and cellular phones for prescribing certain drugs.

Specific Issues

Gifts

Gifts from industry are problematic because they are so widespread and because of their potential to influence a physician's objectivity and/or prescribing practices. Medical decisions, by their nature, must be predicated on objective, scientific information (coupled, of course, with the patient's lifestyle and preferences) and not influenced by external factors and biases, such as insurer economics, personal financial interests (kickbacks) or the largesse of drug companies. Not only does "non-rational" prescribing, as it is referred to in the literature, result in higher and often unwarranted drug costs, it can even have serious deleterious effects such as the over-prescribing of broad-spectrum antibiotics. [1, 22].

Several studies have examined the effect of gifts from pharmaceutical companies on physician behaviour. Research shows a strong correlation between receiving industry benefits and favouring specific products [6, 2]. However, interestingly, physicians claim that they are not affected by such gifts [6, 23, 2, 24]. Even more interestingly,

although most physicians do not view themselves as subject to bias, they do admit that conflicts of interest might influence other physicians' decisions [24, 25].

In particular, gifts of nominal value such as pens, notepads or mugs are viewed as not affecting a physician's behaviour. In addition, certain "gifts" such as drug samples are not really viewed as gifts at all, since they are medically related and intended in essence for the patient rather than the physician. One might even suggest that drug samples serve to promote equitable access in health care, since they allow patients to try out products before committing themselves to an expensive product. [6] However, such products are really intended to induce the physician to prescribe the new product, and research shows that when patients run out of a free sample, physicians are more likely to prescribe that same product rather than a less expensive one such as a generic product. [26] In essence, all industry-supplied medical information or products are promotional. In addition, as previously stated, all personal gifts establish an implied social contract of obligation and expected reciprocation. [4]

One position paper, put out by the American College of Physicians in conjunction with the American Society of Internal Medicine, lists the following questions as helpful in gauging whether a gift relationship is ethically appropriate: "What would my patients think about it, what is the purpose of the industry offer, and what would my colleagues think about the arrangement?"

Studies have shown, in fact, that patients' attitudes and physicians' attitudes towards accepting gifts are not always the same. Overall, patients tended to find gifts less appropriate than did physicians – this was true even for gifts that existing guidelines deem acceptable, such as pens, medical books, and conference meals. [12] About half the patients in one study were aware that physicians receive gifts from the pharmaceutical industry. Among those who were not aware, 24% felt that this knowledge changed their perception of the profession. However, more than 90% of physicians accepting a gift were willing to have it generally known, indicating that perhaps physicians overestimate patients' feelings regarding the appropriateness of gifts. [12]

If one accepts that modest gifts that enhance medical practice or knowledge are acceptable, can one set a limit or specific parameters as to what is acceptable? It is difficult to set an exact amount or description, although several countries do so, as mentioned above. However, it is generally accepted that inexpensive gifts for office use such as pens, notepads or calendars meant for educational purposes or patient care such as medical books are more acceptable.

In one USA study, researchers questioned over 100 residents in internal medicine concerning their attitudes towards nine promotions or gifts offered by pharmaceutical companies. Most residents considered 7 of the 9 items as appropriate (the exceptions being luggage and funding for travel to CME conferences). Where differences in the appropriateness of a gift were perceived, they were based more on cost and less on its educational or professional value. As a result, 83% felt that an inexpensive but not educational item such as a pen was appropriate, whereas an expensive yet educational sponsorship for travel to a conference was inappropriate. The authors suggest as an explanation for this phenomenon that some physicians may think that expensive gifts create an appearance of impropriety. Others may object to the cost of gifts being passed on to patients, and yet others may perceive a strong correlation between the value of a gift and its potential to influence prescribing behaviour. [25]

In contrast, another US study refutes the notion that gifts of lesser value or gifts related to a physician's practice are less problematic than others. It states, as its basic premise, that the biasing effect of accepting gifts is accepted as a matter of deliberate choice, that physicians are deliberately choosing to do something unethical. It is therefore not surprising that physicians object so vociferously to the suggestion that gifts create bias. Therefore, guidelines that limit gifts to those of nominal value and related to the practice of medicine stem from the assumption that such gifts are not tempting enough to influence a physician's prescription choices. However, the authors maintain that this deliberate choice view is inconsistent with the social science research which shows that even when individuals attempt to be objective, they are subject to unintentional bias. Therefore, small gifts may be influential. In fact, why do pharmaceutical firms offer these gifts if not to influence a physician's behavior in some respect? The figures cited above for the amount of money spent each year by the pharmaceutical industry are clear evidence that the industry expects and intends that these costs produce some marketing benefit. Because physicians are unaware of this influence, they do not take steps to correct it. As such, policies that make sense if bias is seen as a matter of deliberate choice are unlikely to be effective if bias is unintentional and unconscious. [24]

The authors of this study, members of the Department of Social and Decision Sciences at Carnegie Mellon University in Pittsburgh, cite several earlier studies that show that individuals are unable to remain objective even when they are motivated to be impartial, and even when they are explicitly instructed about it. This shows that such bias is unintentional and unconscious. Furthermore, the studies suggest that self-interest affects people's choices, changing the way the assess information that they will use as the basis for choices. [24]

In addition, disclosure of a doctor's financial interest in a particular product as an antidote to bias can only be effective if patients know how to relate to such disclosure, and how much to discount the doctor's advice in light of the disclosure. In fact, recent social science research suggests that disclosure may even generate the opposite effect. [24]

Of physicians who felt that gift-taking did not influence their prescribing behaviour, explanations offered ranged from the fact that the doctor's clinical knowledge was strong enough, the formulary restrictions severe enough to prevent bias in prescribing, to the fact that the resident's financial hardship and exhausting schedule entitled him to enjoy these rewards. The acceptability of taking gifts was also influenced by so-

cial norms, i.e., did others (particularly superiors) engage in such behaviour? (This may also help explain why residency programs with guidelines yield more residents that comply with restrictions on gift-taking). The bottom line was that most physicians felt that they enjoyed the benefits without being subject to insidious influence on the part of the pharmaceutical industry. [25] This despite the fact that one representative study proved that physicians got more of their information about the drugs they were prescribing from drug advertisements than from the scientific literature. [23]

Research and Conferences

The ACP-ASIM position paper states that "physicians who have financial relationships with industry, whether as researchers, speakers, consultants… or others, must not in any way compromise their objective clinical judgment or the best interests of patients or research subjects…".[6] The rationale for this prohibition is similar to the rationale presented in the case of gifts: financial relationships can impair objectivity and create conflicts of interest. As a rule of thumb, physicians may accept honoraria for teaching, lecturing or research that advances professional knowledge and is commensurate with the work done. In addition, any financial relationship must be disclosed.

According to one US report, in 1996, there were 151,434 industry-sponsored events; by 2001 this number tripled, to 370,348 or an average of more than 1000 such events every day of the year. [1]

Particular care must be exercised when a physician is invited to speak at a conference developed by a pharmaceutical company (as opposed to one merely sponsored by such company). In such cases, the physician must be very careful that the company does not script his or her presentation, but that he/she has full and free professional discretion and independence. Similarly, physicians who participate in industry-sponsored research must guard against bias in publishing results. Physicians with financial ties to industry should refrain from participating in such research, as studies have shown that physicians with such ties are significantly more likely to report findings that support the sponsor's drugs, and not report unfavourable findings. [6]

Conclusions:

The relationship between physicians and pharmaceutical companies is indeed complex, but that is no reason to shy away from an attempt to regulate it. Like so many other complex issues, ignoring it is an option but ultimately not a very successful one, as doing so would damage physicians and patients alike. There is a clear case for the WMA to address these issues in the context of its aims to protect the honour and interests of the medical profession, to assist all peoples of the world to attain the highest possible level of health, and to set some standards, be they general or specific, for this relationship. These standards can then serve as guidance for doctors and industry around the world, and advance the cause of medicine, which, in the final analysis, is the goal of us all.

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Poverty and Health

Changing the common ground: national medical associations, health, poverty, and the Millennium Development Goals – a new initiative.

"A world not advancing towards the Millennium Development Goals will not be a world at peace. And a world awash in violence and conflict will have little chance of achieving the goals. But if the common ground we used to stand on no longer seems solid, we must seek new common ground for our collective efforts."

(Kofi Annan, Secretary-General of the United Nations, at the International Chamber of Commerce Conference on "Global Economic Governance and Challenges of Multilateralism", Dhaka, 17 January 2004)

On the eve of what should be a milestone for global health, Kofi Annan's words have great significance for national medical associations (NMAs) and their members. Next year marks the fifth anniversary of the Millennium Declaration, an historic agreement between nations to overcome the obstacles to human development in the 21st century. In it, poverty, hunger and disease were given a renewed emphasis, and the Millennium Development Goals (MDGs-*see box)* were established as the drivers for change, aiming to halve poverty by 2015 and to combat HIV/AIDS, TB and Malaria. The agenda was ambitious, but the Declaration had consolidated a great deal of the work done by international develop-

The Millenium Development Goals	
Goal	Targets and further information
1. Eradicate extreme poverty and hunger	*Target for 2015: Halve the proportion of people living on less than $1 a day and those who suffer from hunger.* More than a billion people still live on less than US$1 a day: sub-Saharan Africa, Latin America and the Caribbean, and parts of Europe and Central Asia are falling short of the poverty target.
2. Achieve universal primary education	*Target for 2015: Ensure that all boys and girls complete primary school.* As many as 113 million children do not attend school, but the target is within reach. India, for example, should have 95 percent of its children in school by 2005.
3. Promote gender equality and empower women	*Targets for 2005 and 2015: Eliminate gender disparities in primary and secondary education preferably by 2005, and at all levels by 2015.* Two-thirds of illiterates are women, and the rate of employment among women is two-thirds that of men. The proportion of seats in parliaments held by women is increasing, reaching about one third in Argentina, Mozambique and South Africa.
4. Reduce child mortality	*Target for 2015: Reduce by two-thirds the mortality rate among children under five.* Every year nearly 11 million young children die before their fifth birthday, mainly from preventable illnesses, but that number is down from 15 million in 1980.
5. Improve maternal health	*Target for 2015: Reduce by three-quarters the ratio of women dying in childbirth.* In the developing world, the risk of dying in childbirth is one in 48, but virtually all countries now have safe motherhood programmes.
6. Combat HIV/AIDS, malaria and other diseases	*Target for 2015: Halt and begin to reverse the spread of HIV/AIDS and the incidence of malaria and other major diseases.* Forty million people are living with HIV, including five million newly infected in 2001. Countries like Brazil, Senegal, Thailand and Uganda have shown that the spread of HIV can be stemmed.
7. Ensure environmental sustainability	*Targets:* • *Integrate the principles of sustainable development into country policies and programmes and reverse the loss of environmental resources.* • *By 2015, reduce by half the proportion of people without access to safe drinking water.* • *By 2020 achieve significant improvement in the lives of at least 100 million slum dwellers.* More than one billion people lack access to safe drinking water and more than two billion lack sanitation. During the 1990s, however, nearly one billion people gained access to safe water and the same number to sanitation.
8. Develop a global partnership for development	*Targets:* • *Develop further an open trading and financial system that includes a commitment to good governance, development and poverty reduction – nationally and internationally* • *Address the least developed countries' special needs, and the special needs of landlocked and small island developing States* • *Deal comprehensively with developing countries' debt problems* • *Develop decent and productive work for youth* • *In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries* • *In cooperation with the private sector, make available the benefits of new technologies – especially information and communications technologies.* Many developing countries spend more on debt service than on social services. New aid commitments made in the first half of 2002 could mean an additional $12 billion per year by 2006.

ment conferences during the 1990s and presented a clear, well-timed vision, which was both inspirational and feasible.

With the year 2005 approaching, however, the ideals of 2000 lie in disarray. There are now strong indications that none of the MDGs will be achieved by the target date, and many developing countries are increasingly falling behind. Recalling the Declaration of Alma-Ata (1978), Annan cites the breakdown of the mutual bond between peace and good health – also implicit in Alma-Ata's Millennium successor – as the underlying reason for the MDGs slipping off track. Whilst it is certainly true that the post-Millennial world of armed conflict and terrorism has severely tested that bond, there is a risk that an emphasis upon global problems such as these may obscure other factors which are undermining efforts to achieve the MDGs at local, regional and national level. As far as the health-related goals are concerned, these issues are highly relevant, e.g. lack of progress on the goal to reduce the under-five child mortality rate by two-thirds between 1990 and 2015 is frequently attributed, at least in part, to the problems facing health systems in rural areas. If a change to the common ground of 2000 occurs – and Kofi Annan has indicated elsewhere that a high-level review of the MDGs is being planned for 2005 – then it is imperative that "devolved" issues such as these are taken fully into account in the outcome.

Collaboration between national medical associations (NMAs) across the world could play a crucial role in pushing these issues up the agenda. For example, developing nations' NMAs and their members are in a key position to assess the challenges to health and healthcare provision in their own countries. They are also able to provide from the experience of their members a definitive account of the needs of health systems at national, regional and local levels, and the problems faced by those who work to meet those needs. This level of insight could also help to redress one of the perceived imbalances of the MDGs: the undue emphasis on **what** should be achieved rather than **how.** Developed nations' NMAs, on the other hand, are able to relate their experience of providing assistance to developing nations. Do they feel that such support is being directed in the most effective way? How can their governments' policies on the provision of assistance be developed to meet the needs of recipient countries? There is clearly tremendous scope for constructive dialogue on all of these points.

In an effort to stimulate positive action to improve the situation, during the past year the British Medical Association has been working in partnership with the Department for International Development (DfID), the UK government department responsible for promoting development and the reduction of poverty internationally. Our primary aim has been to build our members' awareness of the international development agenda and to encourage them to consider how they can contribute to the campaign to eradicate poverty in the developing world. An overwhelmingly positive response to our initiatives has been received from our members who are keen to become involved in our future work in this area. The aims of this work, however, go beyond raising awareness of individual physicians.

It was recognised from the outset that it is essential to engage with organisations which have substantial experience of developing initiatives to address the health challenges in developing countries. Therefore in January 2005, a Poverty and Health Policy Group was formed, comprising a mix of such UK-based organisations. In early discussions within this group, topics included the impact of migration and health skills drainage from developing countries, and the continuing inhibition of research into "orphan drugs". These are, however, mere indications of the many problems which need to be addressed. As indicated above, it is clear that a vital element in this process is to obtain first-hand evidence which identifies the obstacles to achievement of the MDGs. *In this respect, the contribution of NMAs and their members is essential.* It is hoped therefore that NMAs will provide this vital input into the process of containing the health threats associated with poverty and realising the aims of the MDGs.

MMC

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WMA

Activities of the President

During the first six months of his WMA Presidency, Dr. James Appleyard has been extremely busy as the following highlights of his activities demonstrate.

In *South Africa* he attended and addressed the South African Medical Association meeting on Strategies for the Survival of Doctors, where the profession is united in pursuing the ethical standards underlying medical practice and in seeking improved healthcare services for those under-served in the population.

In *Uganda* he participated in a series of meetings to arrange training seminars for 250 health professionals and 125 lawyers on the principles underlying the Istanbul Protocol.

On another occasion he joined in a WHO-sponsored meeting, at which a draft constitution for the Federation of East African Medical and Dental Associations was considered. WHO is looking to this body for assistance with medical education, disease surveillance and prevention, including a programme of measles vaccination.

The President gave a guest lecture at the Oral Health Planning Conference in the African Region, organised by WHO and the FDI (International Dental Federation). This important regional conference produced a Consensus Statement on Oral Health (the Declaration of Nairobi). This was a good demonstration of the effectiveness of collaborative working at national and local level on clearly defined and agreed objectives. He also addressed the Annual Assembly of the Ugandan Medical Association on "The right of a child to health care".

In *Taiwan*, attending the International Conference on Influenza and the Resurgence of SARS, the President spoke of the WMA interest and role in such outbreaks and of the work group led by the Canadian Medical Association. He also visited the Chinese Medical Association, the Taiwanese Medical Association, the Bureau of Health Promotion, the Joint Commission on Hospital Accreditation and the National Health Research Institute, noting particularly the role of the Bureau of National Health Insurance whose emphasis was on purchasing Health - not Health Care!

In the *USA* Dr. Appleyard addressed the American Academy of Pharmaceutical Physicians in Miami on "How we should treat our children", and had some discussions on the Declaration of Helsinki. At the Hispanic Development Foundation at *Oregon* Health and Sciences University, Dr. Appleyard gave the guest/keynote lectures on "How does the world treat our children". Visiting the International Department of Cornell University and New York Medical College, he sought support for and recognition of the need for all students to extend their experience through an elective in a developing country.

At the *UK* International Water Summit in London, video-linked with *Brussels*, the President spoke on the relevant health issues relating to the developing world and the need for collective support. In Brussels also, addressing the European Forum for Good Clinical Practice, he emphasised the pivotal role of the Declaration of Helsinki in the ethical framework for research on children and of the WMA Declaration of Ottawa on the Right of a Child to Health Care. He also stressed the importance of the role for the EU in supporting poor countries where the burden of infectious disease impaired their economy.

Other concerns involved the many other vital issues relating to human rights. These include the case of Dr. Biscet imprisoned with three colleagues in Cuba, the deteriorating situation in Zimbabwe where there is increasing under-five child mortality, and the need for support of doctors on both sides of the Israeli/Palestine conflict.

WMA

The 167th WMA Council meeting in Divonne 13-15 May 2004

The WMA Council held its 167th meeting in Divonne (France) in the presence of members of the standing committees and a number of observers. Many also attended the first Conference of the World Health Professions Alliance, held in Geneva on the following two days (see WHPA p. 32).

Following the opening by the Chairman, Dr. Yoram Blachar, and adoption of the 166th Council minutes, the Council received the reports of the President (see above) and of the Secretary General.

Dr. Delon Human in his presentation highlighted the following important developments since the Helsinki meeting:

- the work of the Medical Ethics Unit under the direction of Dr. John Williams. The first draft of the Manual on Medical Ethics should be available by the Tokyo meeting;
- collaboration with the World Health Organisation (WHO) has significantly strengthened, and WHO has confirmed its wish to remain in official relations with WMA. Positive projects or activities include participation in the negotiations and debates leading up to the adoption of the Framework Convention on Tobacco Control;
  inclusion of WMA in the WHO Global Alert and Response Network to combat communicable diseases. This has been updated to deal more effectively with epidemics such as SARS. In this connection the Secretary General paid a special tribute to the outstanding work of the Canadian Medical Association;
  the development of policy on "Violence & Health", and participation in the WHO launch of this project;
  development of policy on safe injections with the WHO section "Safe Injection Global Network" (SIGN);
  Survey of Human Resources for Health Care;
- Adoption in Helsinki of the resolution designating an annual "Medical Ethics Day" to be marked by WMA members on 18th September, the anniversary of WMA's foundation.
- Restructuring the content and format of the World Medical Journal now in its 50th year, under its new Hon. Editor in Chief, Dr Alan Rowe, with future greater orientation towards medical ethics, physician-related human rights and to other issues. Particular tribute was paid to the work of Dr. Ivan Gillibrand as Executive Editor since 1986 and to that of Professor Elmar Doppelfeld, the Co-Editor.
- Continuing growth and effectiveness of the World Health Professions Alliance (see WHPA p. 32)
- the development of a new website devoted to health care technology, and the webcasting of the Helsinki Scientific Session.
- progress with the Human Rights programs: also, the WMA anti-torture project jointly with the International Rehabilitation Council for Torture Victims (ICRT) has gained increasing momentum, and some WMA leaders have visited the five pilot countries to help develop training material and centres for physicians in them.

Turning to membership he reported that the Medical Associations of Armenia, Bangladesh, the Bahamas and Kazakhstan had joined the WMA.

Dr. Human concluded his report by indicating his intention to resign after the seventh anniversary of his appointment later in the

year. He would, of course, continue for the necessary transitional period after the Tokyo General Assembly.

Strategic plan

In preparation for discussions on the future strategy of WMA which was a major topic throughout the Divonne meetings, Council members were asked to respond to three questions. These were to identify what were the most pressing problems for their NMAs, which single issue their members considered to be the most important priority, and what their NMA considered to be the most important priority for the WMA.What was most impressive in a variety of responses was the undercurrent of recognition of the pressures on professionalism at all levels of society, and the need for the medical profession to consider both its relationship with society and its own identity (see boxes A and B).

The Chairman commenting that the discussion of these replies reflected a number of common problems, the most notable relating to health care systems said that WMA has a vital role to play in identifying answers to these problems.

World Health Assembly

Council discussed the World Health Assembly which would take place the following week. In this connection Council welcomed the inclusion of members of NMAs in an increasing number of delegations to the Assembly.

Medical Ethics

Council considered the report of the Medical Ethics Committee.

Declaration of Helsinki

After receiving the report and its recommendations, – "1. That para. 30 be not amended; and 2. That the Medical Ethics Committee at its May meeting decide whether either an accompanying statement or preamble for the DoH, or a note of clarification for para. 30, be developed," Council adopted the recommendations, and after a short debate a motion that the recommendation be referred to NMAs for comment was defeated.

The recommendations (in boxes C and D) were adopted for referral to the General Assembly in Tokyo.

The following note outlines the discussion in the Medical Ethics Committee on the report and recommendations of the working group, and the comments already received on them.

Several members in supporting the recommendation that there be no amendment, observed that the debate had continued for a considerable period of time, and that the longer it went on the more it could weaken the status of both the DoH and the WMA. Attention was drawn to the problems relating to the European Union Clinical Research Directive and the position of the FDA, which didn't accept the current DoH because of paragraph 30. A plea was made for a separate statement on access to care not being related to ability to pay. The Secretary General observed that the FDA would not feel able to accept paragraph 30 even if amended. This also applied to EMEA. An opposer to any amendment commented that the problems related to health care systems should be considered separately and that one could then return to the DoH. The AMA proposed that the words "it is important to consider post-trial access (to treatment)" be considered. There was a real need to talk about access to treatment.

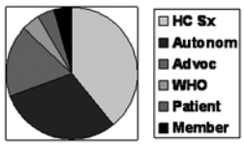
Agreeing that there should be no change, three members were opposed to a preamble but would accept an explanatory document. It was also suggested that paragraph 30 should be considered as aspirational, and that the real issues were those of justice and equity. The speaker could accept a note or preamble which didn't weaken the DoH and suggested that a draft declaration on the right to health be available in Tokyo. Meanwhile a moratorium (later withdrawn) on further discussion for two years after Tokyo should be considered. This would not inhibit discussion but there should be no formal proposal for change during this period. Later, in clarification it was made clear that this would not inhibit any action were there to be some remarkable breakthrough or change of circumstance.

A strong plea was made however that, bearing in mind that the FDA and EMEA would not change, paragraph 30 should be changed.

The first recommendation was then put to the vote and was approved with one vote contra and no abstentions.

(A) Most Pressing Problem to NMAs (n=17)

- Health Care System Problems (9)
- Professionalism & Autonomy (7)
- Advocacy (4)
- Member- related (communication) – (1)
- Patient-related – (1)
- WHO – (1)



(B) Most Important Task for WMA (n=17)

- Health Care System Problems / WHO / Public Health (5)
- Communication / Info / Network (3)
- Ethics (3)
- Advocacy (1)
- Finances(1)
- Professionalism (1)
- Human Rights (1)

(C) Recommendation to General Assembly

1. That there be no change to paragraph 30 of the Declaration of Helsinki.

Reference was then made to a suggested note of clarification from Dr. William Steiger (US Dept. of Health and Human Services). Bearing in mind the problems associated with an insertion into the preamble, it was then proposed that this be a note of clarification of paragraph 30, analogous with the note concerning paragraph 29.

After an extensive debate and some modification of the wording, the following form of wording for the note of clarification to paragraph 30 was adopted as a recommendation.

(D) Recommendation to General Assembly
2. Addition of a Note of clarification to paragraph 30

"The WMA hereby reaffirms its position that it is necessary during the study planning process, to identify post-trial access by study applicants to prophylactic, diagnostic and therapeutic interventions identified as beneficial in the study, or access to other appropriate care. Post- trial access arrangements or other care must be described in the study protocol, so that the ethical review committee may consider such arrangements."

Clinical trials in Populations with Insufficient access to Health Care

The Committee considered a Proposed WMA Statement on "Clinical Trials in Populations with Insufficient Access to Health Care" and agreed that the Finnish Medical Association would review this in the light of the recommendations on paragraph 30 of the Declaration of Helsinki.

Relationship between Physicians and Commercial Enterprises (also see article p. 33)

This subject will be further discussed at the October WMA meeting.

The meeting heard a plea from the Bulgarian delegate to WMA on behalf of the doctor and five nurses imprisoned and condemned to death in Libya for allegedly infecting more than 400 children with AIDS, in spite of expert evidence of their innocence.

The Chairman of Council has appealed to the Libyan authorities to quash this sentence.

Socio-Medical Affairs

Dr. Henry Haddad was elected Chair of the Socio-Medical Affairs Committee.

Water and Health Care
Council approved a proposed Statement on Water and Health Care, to be forwarded to the General Assembly.

Armed Conflict
Council approved amendments to the Regulations in Time of Armed Conflict, to be forwarded to the General Assembly.

Quality Improvement in Medical Education
Council approved a proposed WMA Resolution on Global Standards for Quality Improvement of Medical Education, to be forwarded to the General Assembly

Health Emergencies Communication and Coordination
The Recommendations of a proposed WMA Statement were approved as a Council Resolution (box, p. 44)

Council also approved circulation of the proposed Statement and set up a Work Group to develop a plan for the establishment of a global physician network to improve preparedness for health emergencies.

Finance and Planning

Dr. J. C. Nelson was elected Chair of the Planning and Finance Committee.

Finance
Subject to an unqualified audit opinion, the Financial Statements for 2003 **were approved.**

Santiago 2005
Council approved the themes for the Scientific Session and the arrangements for the 2005 General Assembly in Santiago. The themes will be "Health Care Systems Reform" and "Access in Medicines".

Policy review
Council endorsed the recommendation that the Secretariat should develop a simplified process for review of existing WMA policies.

Membership
Recommendations that the applications for **constituent membership** of the **Medical Associations of Estonia and Vietnam** be forwarded to the General Assembly, **were approved.**

An application for **cooperative relations** with WMA from **Project HOPE, was approved.**

Official Languages
Council approved the establishment of a work group of officers to review the problems of official languages of the WMA.

Obligatory notification of AIDS as an infectious disease
Council also referred an emergency proposed Council resolution that AIDS be classified as a notifiable disease, to the Socio-Medical Affair Committee.

Zimbabwe
The Council discussed its serious concerns about reports of the collapse of the health care system in Zimbabwe and **mandated the WMA leadership** to investigate the situation in Zimbabwe and take appropriate actions.

Strategic Plan
The Council concluded with a further debate on a Strategic Plan in which many issues were aired and discussed. It was decided that a survey should be commissioned, to be overseen by a working group; a full report of discussions would be sent to NMAs and that the business group looking at non-dues issues report to the supervisory group, to whom it would where appropriate act as a tool.

Succession of Secretary General
The Council approved actions necessary to identify a new Secretary General.

Council Resolution on Health Emergencies Communication and Coordination

1. That the WMA and member NMAs should work closely with WHO, national governments and other professional groups to jointly promote elements of this policy.
2. That the WMA urge physicians to be
   - alert to the occurrence of unexplained diseases and deaths in the community,
   - knowledgeable of disease surveillance and control capabilities, and
   - assiduous in the timely reporting of suspicious cases of illness to appropriate authorities.
3. That the WMA encourage physicians, NMAs and other medical societies to participate with local, national and international health authorities, in developing and implementing disaster preparedness and response protocols for natural infectious disease outbreaks. These protocols should be used as the basis for physician and public education.
4. That the WMA call on NMAs to promote and support the GOARN network as a control coordinating entity in combating global health security threats.
5. That the WMA call for the establishment of a strategic partnership agreement with WHO, so that in the case of epidemics, health communication can be stepped up considerably and two-way flow of information ensured.
6. That WHO should coordinate the development of an inventory based on existing stockpile supplies, so that such supplies can be rapidly deployed and accessed by physicians involved in the care of victims.
7. That international agreements should be proactively explored to facilitate the movement of health professionals who are involved in the management of epidemics.
8. That research in the field of emergency preparedness should be enhanced by national governments and NMAs where appropriate, to better understand current flaws in the system and how to improve preparedness in the future.
9. That education and training of physicians should be amended to take into account the realities and specific needs required in the event of emergencies, and to ensure that due diligence is paid to patient and healthcare worker safety when managing patients with acute infectious diseases.
10. That physicians everywhere in the world, including Taiwan, should have access to WHO programmes and information, and information concerning health emergencies.

Medical Science, Professional Practice and Education

Preventing preventable chronic disease – international developments

Sir Alexander Macara, FRCP, President, National Heart Forum, UK

Two important actions in the past year mark significant potential for the future control of the major causes of morbidity and mortality from non-communicable diseases. They are the publication of the results of the global heart disease study MONICA, and the endorsement by the World Health Assembly of the Global Strategy for Diet, Physical Activity and Health. The following overview of these and other developments comments on the underlying factors influencing progress in this area and the importance of collaborative action.

As the frequency of many non-communicable diseases (NCDs) – notably heart and circulatory disease, cancers and diabetes – increases in developed countries and are alarmingly superimposed on the continuing burden of communicable disease in developing countries, the need for effective and concerted international action to attack their root causes is urgent.

Since the Alma-Ata initiative of the WHO and UNICEF in 1978 it is accepted wisdom that there are three main thrusts in all health policy – control of adverse environmental factors, the promotion of healthy life-styles, and the reorientation of health care services towards prevention and early diagnosis and treatment. The intervening quarter-century has shown the crucial significance of two factors – one internal to the health sector of society and its governance, the other external to it. The internal factor is the lack of basic knowledge and consequently the inadequacy of the evidence, which is required to stimulate policy-makers and to goad decision-makers; the lethal nature of tobacco is a notable exception to this deficiency. The external factor is the globalization of markets for consumer products which should be a force for economic and social progress but which poses a growing threat to health, especially in developing countries, when the profit motive mocks any ethical considerations.

These two factors point to two absolute priorities. The first is the essential criterion for informed policy and action of accurate and reliable epidemiological information about time, place and persons. The second imperative is to apply all the evidence obtained from epidemiological studies to underpin and improve existing programs, to inform development in international collaboration, and to combat the inimical effects of irresponsible commercial activities.

The good news is that there are grounds for qualified optimism in the outcomes of recent collaborative activities and in the ferment of current policy proposals which call

for international collaboration between non-governmental organizations (NGOs) and intergovernmental organizations (IGOs) such as WHO and the European Union. The outstanding example of international collaboration is the MONICA study, "the world's largest study of heart disease, stroke, risk factors and population trends" which WHO was instrumental in establishing and supporting. The compilation of the resultant monographs, edited by Professor Hugh Tunstall-Pedoe of Dundee, is now available from WHO in hard copy and in CD-ROM, the MONICA Monograph and Multimedia Sourcebook (WHO 2004) (www.ktl.fi(monica). This presents unique data on CVD factors, mortality and morbidity and medical care from 21 countries over four continents involving 38 research groups from 1979 to 2002. It offers challenging hypotheses about the relationship between risk factors and changes in the pattern of CVD, and is a unique and invaluable resource for clinicians, public health practitioners, researchers, policy-makers and students. It is particularly to be praised for acknowledging the difficulties involved in such a complex exercise.

In this context, it is timely that WHO has developed its STEPWISE (STEPS) approach to surveillance of risk factors (2003) relating to NCDs. This aims to provide standardized materials and methods to help countries, especially those that lack resources, to initiate NCD activities. The goal is to achieve quality data compatibility and comparability over time. WHO is maintaining the NCD data at a country level on the WHO Global NCD InfoBase.

WHO has shown superb leadership in forging the Framework Convention on Tobacco Control (FCTC) – its first-ever global health convention. This will proceed to implementation in September 2004 assuming ratification by the requisite forty countries. Further, in May 2004, the World Health Assembly also approved a Global Strategy for Diet, Physical Activity and Health. Although this does not have the force of a binding treaty, it marks a significant advance in setting out standards of good practice for competent national public health strategies. Predictably, those elements of this strategy which require collective governance, such as effective controls on the marketing of foods high in fat, sugar, and salt, may also become the subject of another international convention.

Dr. Derek Yach and Dr. Corrina Hawkes of WHO have just published a compelling framework for action – "Towards a WHO long term strategy for the prevention and control of leading chronic diseases" (2004). This has as yet no formal status, but it raises many fundamental and controversial issues, notably the health impact of foreign direct investments in developing countries. It calls for global cooperation between the WHO and other IGOs such as the World Bank and the World Trade Organization in tackling the global epidemics of linked avoidable chronic diseases.

International NGOs such as the World Health Federation, the International Diabetes Association, the International Obesity Task Force, the International Association for the Study of Obesity and the Cancer Leagues are increasingly making a significant contribution to the prevention of avoidable chronic diseases. They are key civil society stakeholders and act in particular as a countervailing force to the market-driven vested interests of the corporate sector. They share a common agenda for collective action and are closely involved with WHO in advocating and shaping evidence-based strategies for action. The most recent example was to counter the influence of the sugar industry at this year's World Health Assembly. Similar action by NGOs is taking place within the European Union. The European Heart Health Network (EHN), whose membership comprises national heart foundations which are increasingly active in public health advocacy, has worked closely with international cancer organizations in pressing the EU institutions to introduce tobacco control measures such as banning advertising and sponsorship throughout the EU. It is now embarking on a project to investigate the extent of the marketing of foods high in fat, sugar and salt to children in Europe and the effectiveness of any national controls.

The prevention of linked avoidable chronic diseases at all levels will be greatly enhanced by greater strategic collaboration between NGOs, which share a common agenda. Action on tobacco control, food and nutrition and the promotion of physical activity are obvious priorities. A national example of collaboration is the UK's National Heart Forum (www.heartforum.org.uk), which brings together the leading national professional and social policy NGOs which are concerned about the causes and effects of heart disease, strokes and diabetes, to develop and advocate collective public policy positions.

The bad news is that those transnational companies whose activities are inimical to health, frequently escape controls due to the absence of structures and mechanisms for international action. The prevailing "new-liberal" approach by most governments is minimal intervention, with non-binding partnership agreements or dependence on self-regulated corporate social responsibility (CSR) in the jargon). International Public Interest NGOs (PINGOs) have a putative role in the promotion of CSR, but that approach has proved to be sadly futile in the absence of international standards and any meaningful involvement of independent civil society monitoring and audit. As the open-ended extrinsic economic, social and health costs of uncontrolled commercial activity are borne by society, it must be right that society is involved in its regulation.

The Director-General of WHO, Dr LEE Jong-wook, pledged in July 2003 to develop and implement a comprehensive plan for combating the preventable chronic NGOs, which account for a growing share – estimated at 60% – of the burden of disease world-wide. Tackling the power and influence of irresponsible transnational companies will require continuing strong leadership by WHO and other international IGOs working closely with health NGOs. This is a particular challenge to the health professionals. In the global war against disease, we are in the forefront of the battle. We must not fail.

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Genomics

Strategies in the Battle Against Malaria

The fight against malaria over the past twenty-five years or so has been a story of success and disappointments. The discovery of various drugs has advanced and improved the control of the disease but also unfortunately resistance caused problems and currently, this remains a major problem. Now the complete sequence for Homo sapiens and Plasmodium falciparum is known, new strategies can be worked out in the world-wide battle against malaria. It is anticipated that new targets for drugs will be identified – and that drugs in future will be computer-designed to attack at metabolic and genetic weak points. If the present armamentarium of anti-malarial drugs fails to act against resistant parasites, there is hope that new classes of drugs will achieve more effective cures and ultimately eradication of malaria.This article reviews the scene and the exciting possibilities for definitive mechanisms for dealing with the remaining problems which can flow from the genomics revolution.

Tackling rising levels of medicine resistance is one of the key challenges to African States in their efforts to control malaria and meet the declared target of saving the lives of half the 800,000 children who die of the disease each year by 2010. Recognising that the cheapest and most readily available medicines are increasingly ineffective, the WHO "Roll Back Malaria" programme urges countries to switch to the combination therapy, *Artemisinin-based Combination Therapies (ACT's)* when there is strong evidence that existing conventional medicines are no longer working. As ACT's combine two medicines which work in different ways, it is unlikely that the malaria parasite which has rapidly developed resistance to other single treatments will evolve to resist these medicine combinations. WHO added the ACT's (Artemether/lumefantrine) to its Essential Drugs List. Furthermore, the Global Fund Against AIDS, BTB and Malaria funded proposals to "Roll Back Malaria" in Zanzibar and Zambia which included purchasing and phasing-in the use of new ACTs. Expressing the hope that this Fund and other funding mechanisms would be used to purchase ACT's where they are needed to treat and control malaria, Dr. Gro Harlem Brundland, stressing the need to reduce their prices in developing countries said "It is important that countries, which need ACTs are able to access and use them in a sustainable manner".

Many countries in Eastern, Central and Southern Africa are experiencing resistance to chloroquine, and resistance is also appearing in West Africa. As a result many countries have moved to sulphadoxine-pyrimethamine ("SP" or "Fansidar") as a first line treatment, but resistance to SP is also spreading.

There is new evidence that the number of child deaths due to malaria is increasing due to failing medicines and medicines of poor quality. There is also evidence that due to rising levels of medicine resistance, almost half the money spent on anti-malarials is being used to pay for inappropriate treatment. This also highlights the need for more efforts on preventing malaria using proven cost-effective measures such as insecticide-treated bednets.

The WHO recommendation is that countries begin the transition of medication as soon as levels of resistance exceed 15% and that the change will be implemented before resistance reaches 25%.

The rise of resistance

Halofantrine, which like mefloquine was produced as a direct result of the Vietnam War, is highly effective against multi-drug resistant Falciparum malaria. Unfortunately, during clinical evaluation in Thailand – after it had been registered in several countries – halofantrine was found to predispose to potentially lethal cardiac arrhythmias. Its use is now restricted.

There has been a global initiative to evaluate artemisinin-based combination treatments throughout Africa and South America. The artemisinin combinations provide consistently rapid resolution of symptoms, they are highly effective and well tolerated, and in low transmission areas, use of the combinations provides the bonus of reducing malaria transmission and therefore the incidence of malaria.

The rediscovery of artemisinin and the synthesis of piperaquine, lumefantrine and pyronaridone in China have provided a new generation of effective, well-tolerated, and in some cases affordable, countrywide anti-malarial drugs rather than time-honoured quinine, and may be effective.

Double Act

Combination therapy – combining two drugs together to prevent the evolution of resistance – is a practice already used for the treatment of tuberculosis, leprosy, HIV, and many cancers. As the probability of the development of a mutant resistant to one compound is very low, simultaneous resistance to a combination is therefore extremely unlikely to emerge.

Thus, in order to prevent resistance to the artemisinins, these drugs are being combined with other synthetic compounds. As artemisinin works quickly and is removed from the body rapidly, these additional compounds should be those that last longer in the body, mopping up any parasites that have escaped.

The malaria genome project

Within the genome of Plasmodium falciparum are the genes that make this malaria parasite so deadly to humans. However, to date deciphering the genome in terms of weak spots in the sequence, and on/off switches used during development, has been difficult. Despite its relatively small size – the human genome is 100 times larger – the nature of the malaria genome has remained elusive. Each of the 14 malaria chromosomes has its own set of genes, but they all have highly conserved central regions, and highly diverse regions near the

telomeres at the ends. There are 22.8 million bases (Mb) of DNA, of which complete sequences are available for chromosomes 1-5, 12 and 14. The other chromosomes still have some gaps remaining that are being "closed up".

Within the genome, 5279 genes have been identified. Only 40% of the proteins expressed by the genes resemble others in databases, where a similarity often suggests what their function might be. So around 60% of the proteins may well be unique to this organism, which is a very high percentage in comparison with other sequenced eukaryotes. This reflects both a massive evolutionary distance and a highly specialised ecological niche occupied by this organism. The subtelomeric regions are of particular interest because they contain highly variable gene families, a variation due largely to the deletion or insertion of DNA sequences, that help the parasite evade the human immune system. They are also highly diverged between species of Plasmodium and undergo high levels of recombination, which generates further diversity.

Insights into metabolism

Only 733 of the 5277 genes have been identified as enzymes, proteins that make the parasite tick, driving the metabolic pathways that build up or break down the organism's tissues for parasite use. Not only is this a lower percentage than in all other sequenced organisms, but the parasite also appears to lack some key biosynthetic pathways. For example, it has little capability at all for making purines – the adenine (A) and guanine (G) in DNA.

Most of the biosynthetic pathways in Plasmodium, such as in the synthesis of haem, isoprenoids and fatty acids, appear to be localised in the apicoplast, a structure within the cell that has its own genome, and is similar to the chloroplast of plants and algae. Although this genome encodes for only 57 proteins, it is calculated that around 10% of the proteins expressed genetically by the nucleus may come from this structure.

Some of the metabolic pathways identified are not present in humans, and therefore are potential targets for novel drugs and indeed, the availability of new possibilities for anti-malarial drugs.

Insights into pathogenesis and immune evasion

The particular danger Plasmodium falciparum presents to humans is due in part to the way it can modify the surface of the host red blood cell in which it grows. Approximately 16 hours after invasion, parasite-producing proteins can be detected on the surface of red blood cells. These then mediate adhesion to a variety of host molecules on endothelial cells and some other cell types. Infected red blood cells do not circulate as normal, but instead accumulate in the small blood vessels in a variety of organs, where they may initiate life-threatening complications. The host immune system is aware of these changed surface proteins and launches a protective antibody response. Yet the parasite is able to avoid this response by regularly switching between different versions of the proteins – a trick known as antigenic variation.

The main benefits likely to come from the genomes of host and parasite will be analysis of data using high throughput technologies of gene expression. Knowing the gene sequences means DNA microassays can be designed to look at the changes in gene expression, for example, during the cell cycle and during drug treatment. Such novel techniques will help identify the pyramidal networks of genes that are regulated in unison – and shed much light on the way genes are involved in drug resistance.

Furthermore, the complete genome will enable proteomics to identify all the proteins produced in the different stages of the cell cycle governing the parasite's existence, or in different compartments within the cell.

Conclusion

Big international science combined with medicine, utilising high throughputs of functional genomics, will help researchers to understand what the genes of parasite and host actually do. "DNA chips" or "DNA microassays", as a grid of tiny spots of DNA from hundreds or thousands of genes, are used to examine the expression of many genes at once. Subject areas include cyto-adherence; antigenic variation; merozoite invasion of red blood cells; sexual stage biology, gametocytogenesis and parasite development in the mosquito; structural biology of parasite proteins; and bio-informatics.

Using parasites isolated at different stages in their life cycle, DNA microassays will be able to analyse which genes are switched on or off at the various stages. Weak spots will be targeted for drug attack. High-throughput identification of proteins using mass spectrometry will enable crucial genes to be "knocked out" or modified. The structures of proteins in 3-dimensions, and the time dimension, will be analysed to learn more about how molecular orbital theory fits into catalytic function.

As Dr. Tony Holden explains:

"In the last 20 years, only about 20 proteins have been characterised, whereas in the next 10 years, we hope to characterise several hundred key proteins. These findings will feed into applied research for new drugs, treatments and vaccine against malaria."

Ivan M. Gillibrand

Immunodiagnostics

High-Technology Medicine At The Bedside

The interesting technological inventions from the Institute of Bioscience and Technology, Cranfield University, reported below illustrate more potential for the use of "high-tech" diagnostic aids at the bedside.

Diagnosis in Public Health Disorders

H. pylori (HP) infection is recognised as the most common gastrointestinal bacterial disease world-wide. It is now accepted as the major cause of gastroduodenal ulceration in

over 80-90% of patients. Tuberculosis (TB) is another major public health problem, with approximately one-third (1.9 billion) of the world's population infected. Typically, the diagnosis of these infections requires both high-cost instrumentation and highly skilled personnel. This invention provides a rapid device for measuring these bacterial infections at or near the patient's bedside.

Advantages

The use of electronic technology via the nose/nostrils has been successfully developed since its introduction in the early 1980s, primarily aimed at the food industry. This invention exploits this technology further for medical applications, resulting in a device offering a number of advantages for diagnosing bacterial infections, for example:

- The device can be applied to the analysis of gas samples generated *in vitro* from samples obtained from patients e.g. sputum samples
- The device can be used to diagnose and/or monitor gastric and/or lung disorders
- By utilising dedicated software, a fast odour recognition system can be employed, significantly reducing diagnosis time
- Fast inexpensive collection of volatile samples can be achieved
- Storage and rapid analysis (within 10 minutes) of patient data, using a bedside diagnostic system

Applicability

The device is ideally suited to the rapid, cost-effective diagnosis of major bacterial infections of the human lung and stomach.

Technical field

The device operates by a unique enzymatic pre-treatment followed by passing the gas sample over a multiplicity of chemical sensors that generate electrical outputs. These outputs are passed to a data processing system, e.g. a hybrid intelligent system employing a search optimisation engine of genetic algorithms and many neural networks. This determines the distinctive patterns characteristic of particular disease states.

Replication of Nucleic Acid Arrays

DNA analysis is now a vital tool used for a wide variety of application from medical diagnosis and criminal forensics to military and civil defence. Undoubtedly, the use of this technology will accelerate over the coming decades, largely as a result of innovations and improvements to the existing devices. This invention relates to methods for manufacturing nucleic acid arrays and their application in sequencing, detecting and identifying specific nucleic acids. The invention is also directed towards methods for the replication of probe assays, used for screening biological samples for target nucleic acids and nucleic acid variations.

Advantages

Current methods for fabricating arrays suffer from a common limitation, i.e. each array and each element of each array requires a separate synthesis and fabrication protocol which is normally laborious, time-consuming and expensive. This invention overcomes these problems and provides new methods for rapidly and accurately replicating complementary copies of nucleic acid arrays. The solid supports that can be used for the array base include porous or non-porous plastic, ceramics, glass, metals, resins, gels, silicon and semiconductors.

Applicability

The broad scope of this invention means that it can be applied to a wide range of applications, where nucleic acid determination plays a key role including:

- Pharmacology
- Environmental diagnostics
- Medical diagnostics
- Forensic analysis
- Clinical analysis

Technical field

This invention covers a number of methods for producing arrays. Broadly, the methods are based on the use of a pre-formed nucleic acid array (master copy) replicated by bringing it into contact with a blank copy which contains immobilised primers and by initiating specific replication of the nucleic acid sequences either chemically or enzymatically.

Cholesterol in Heart Disease

One of the main causes of death in the developed world is cardiovascular disease and the contribution of elevated blood cholesterol levels to this is well established. There is, consequently, a need to measure levels of cholesterol in order to diagnose the condition and prescribe appropriate dietary or pharmaceutical treatment. This invention provides a rapid, accurate and low-cost approach to measuring cholesterol, based on screen-printed biosensors that can be mass-produced.

Advantages

This is a very easy to use, rapid, low-cost biosensor system that can readily be used by most members of the general public. Indeed, its method of use is very similar to that used by diabetics (throughout the world), who rely on an electrochemical-based biosensor to measure their blood glucose levels. In contrast to most conventional home test kits, used for measuring cholesterol levels, which tend to be colour-based (hence relies on a subjective interpretation of a chart), this sensor provides an accurate quantitative read-out of cholesterol concentrations. In addition, this invention circumvents the lack of well-known direct electrochemical mediators for cholesterol oxidase.

Applicability

The sensor provides an accurate measurement of blood cholesterol levels. However, the format of the device is not limited to cholesterol. In effect, the invention provides a method for detecting almost any analyte that is oxidisable by means of an oxidase with the generation of hydrogen peroxide. The list of potential target analytes includes:

- Glucose
- Amino acids
- Alcohols
- Xanthine (levels of which can be indicative of liver pathology)

This is not an exhaustive list and serves simply to illustrate the potential offered by this invention.

Technical field

The invention is based on a novel use of a horseradish peroxidase substrate, ABTS, as a mediator in an electrochemical enzyme electrode.

Preparation of Biologically-Active Molecules by Template Polymerization

This invention provides an innovative method for the synthesis of biologically-active molecules (e.g. drugs, effectors, modulators, inhibitors), providing a powerful tool for many applications in analytical chemistry. The synthetic molecules have a structure that is complementary to that of the original template, i.e. it is a replica that resembles the drug molecule. However, compared to the conventional methods for producing biologically-active molecules this approach is quicker, easier and hence low-cost.

Advantages

Previous efforts in drug design have typically been based on the cumbersome investigation into the structure-activity relationships of a large number of chemical structures. This invention provides a much more simple and direct method to design biologically-active substances.

Applicability

This invention can be adapted to provide biologically-active molecules, derived from a wide range of receptors including:

- Enzymes and nucleic acids
- Cells, prions and viruses
- Tissue samples and drugs

Hence, once prepared these molecules have a wide range of applications, e.g. used as drugs for pharmacology and medicine, as receptor-specific ligands in analytical chemistry (sensors, assays) and for separations in the biotechnology and pharmaceutical industries.

Technical field

The biologically-active molecules are synthesised using the following sequence of events: 1) polymerisation of functional monomers in the presence of a biological receptor, 2) separation of the complex formed, 3) removal of the template molecule, and 4) solubilisation of the synthesised replica. Synthesised using this method, the target molecules (dimers, oligomers, polymers, or a mixture of these compounds) can rebind either *in vitro* and/or *in vivo*.

A Novel Building Block Approach for Designing Affinity Ligands for Glycosylated Haemoglobin

The exponential increase in the number of structures available in the Brookhaven Protein Databank has led to a growing interest in the direct approach to drug design. Based on the development, this invention exploits the tools developed and used by pharmaceutical companies to aid the development of synthetic receptors.This invention provides the novel concept of using a "building blocks" approach for designing affinity ligands; significantly enhancing the potential for constructing specific sensor systems that, hitherto, would have proved to be extremely difficult.

Advantages

Using this technology it is possible to characterise the target protein molecule efficiently, estimate the interactions between individual combinatorial "building blocks" and any proposed binding site, *rationally* designing new peptide sequences and also to investigate the interaction between lead ligands and the binding site. Hence, the invention provides a highly efficient and effective method for the design of "bespoke" synthetic receptors. This is a distinct advantage when it is desirable to either replace a less robust, biologically derived, receptor or to designing a ligand for a particular sensor system when no such (biological) element exists.

Applicability

This invention can be used for a number of applications including:

- The rational design of new peptide sequences
- The rational design of synthetic receptors that could be used in conjunction with a wide range of sensor systems, e.g. amperometric, potentiometric, optical, magnetic and gravimetric based transducers

Technical field

This invention relates to the generation of synthetic affinity ligands. It is based on a three-domain approach that can be generally applied to the design of artificial ligands, intended for analytical purposes. These domains are comprised of recognition, affinity, and flexible components, each domain fulfilling a specific function. The design of each is obtained through a virtual screening of chemical databases.

An Intelligent Volatile Pattern Analyser for Diagnosis of Urinary Tract Infections *in vivo*

Urinary tract infections (UTI) are a significant cause of morbidity with around 3 million UTI cases each in the USA alone. Thirty-one percent of nosocomial infections in medical intensive care units are attributable to UTI. Current diagnostic techniques require 24-48 hours to identify pathogenic species in urine midstream specimens. Despite the introduction of molecular tests, culture remains the gold standard in everyday clinical practice. This invention greatly reduces the time required to carry out a diagnostic test. Based on the use of an intelligent diagnostic model, detection and recognition of UTIs can be accomplished within 5 hours of the receipt of specimens in the laboratory.

Advantages

The application of this novel technique, combining sensor technology with artifical intelligence, offers the opportunity for rapid and accurate discriminating between different infective organisms in fresh samples of urine. Based on this invention, future developments could lead to a new generation of diagnostic instruments capable of providing rapid detection of infectious agents *in vitro*

WHO

and *in vivo*, with enormous implications for future clinical practice.

Applicabilitiy

This apparatus will be ideally suited for use in a hospital laboratory environment, where the rapid (and hence more economical) determination of UTIs can be achieved.

Technical field

The apparatus comprises a vapour or gas generating system which, by interaction with a urine sample, produces volatile chemicals that are characteristic of infection. The product of this interaction is then delivered to a detection system in a precise and reproducible way. This detection system comprises an array of sensors, each having a different sensitivity to potential components of the gas stream. An electrical output signal is generated in response to these components. A data processing system then analyses this output signal, providing a profile of the urine sample – highlighting any UTIs.

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Commission on Intellectual Property Rights, Innovation and Public Health

The Commission on Intellectual Property Rights, Innovation and Public Health held its first meeting on 5-6 April at the World Health Organization (WHO) in Geneva. The Commission was established as a result of a World Health Assembly Resolution in 2003 which called for WHO to establish a time-limited body to "produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries."

Welcoming the members of the Commission, Dr. LEE Jong-wook, Director-General of WHO, said: "Making treatments available for diseases associated with poverty has been a major priority for WHO ever since the organization came into existence. These diseases confront us with highly urgent needs that are usually extremely difficult to meet. Bold and innovative thinking is required – not only to find technical solutions but to find economic, social and political ones as well."

The Commission held discussions with senior officials from WHO, representatives from international organizations (UNCTAD, UNAIDS, WIPO, WTO), from the research-based pharmaceutical industry and from civil society.

In her opening remarks, the chairperson of the Commission, Ms Ruth Dreifuss, said: "The advance of medical science is of the utmost importance in attacking these problems. The issue we are asked to address is that medical science tends to focus disproportionately on diseases and ailments of the developed world."

The Commission agreed on a policy of openness in consulting the many different stakeholders with an interest in its work, and in drawing on the expertise they have to offer in supporting the work of the Commission. It requested the Secretariat to compile a register of stakeholders and individuals with expertise to offer. Its publications, and submissions received by the Commission, will be placed on the Commission website.

World Health Report 2004 and the World Health Assembly

The World Health Report 2004 has as its main theme the problem of the pandemic of HIV/AIDS and concentrates on the call for a comprehensive strategy linking prevention, treatment, care and long-term support. It stresses the need for international organisations, national governments, the private sector and communities to combine their strengths to tackle HIV/AIDS and in parallel, strengthen their health systems, which will also benefit whole communities. The World Health Assembly itself reflected both the immediacy of the HIV/AIDS crisis and the importance of improving public health in the resolutions it adopted. This was summed up by the comment of Dr. LEE Jong-wook, WHO Director-General, that "This World Health Assembly clearly raised the bar for improving public health of all people".

(A *full comment will appear in the next issue of WMJ-Ed.)*

WORLD HEALTH ASSEMBLY RESOLUTIONS 2004

WHO Global strategy on Diet, Physical activity and Health

Health Promotion and healthy lifestyles

Reproductive health

Resolution on the family and reproductive health

Response to HIV/AIDS

Global effort to eradicate Polio

Guinea-worm disease

Buruli ulcer

Human African Trypanosomiasis

Reducing Measles deaths

Human organ and tissue transplantation

International migration of Health Personnel

Framework Convention on Tobacco control

Quality control

Action Against Substandard and Counterfeit Medicines

Asian and African Countries Move to Improve the Quality of their Medicines

Geneva – The World Health Organization has launched an action plan against substandard and counterfeit medicines with six countries from the Greater Mekong subregion. The plan follows similar initiatives in Africa and will continue to expand in response to countries' increasing call for assistance to improve the quality of their medicines.

Counterfeit and substandard medicines are frequently detected in Cambodia, China, the Lao People's Democratic Republic, Myanmar, Thailand and Viet Nam and the problem seems to be increasing. Products most commonly counterfeited in this region include antibiotics and those used in the treatment of tuberculosis, malaria and HIV/AIDS. The use of poor-quality or counterfeit medicines has little or no therapeutic effect and in poor settings often leads to death.

"Combating low quality or illegal medicines is now more important than ever. Expanding access to safe, effective treatment for AIDS and other illnesses is no longer an option, it is an imperative," says Dr LEE Jong-wook, WHO Director-General.

At a meeting from 11-13 November 2003 in Hanoi, Viet Nam, WHO and the six countries kick-started joint activities directed at key decision-makers, health professionals and the general public to strengthen inspection and post-marketing surveillance.

Substandard medicines are thought to account for 8.5% of medicines on the market in Thailand. Eight per cent of randomly collected samples in Viet Nam and 16% in Myanmar failed laboratory testing for quality assessment. From these batches, Rifampicin (used to treat tuberculosis) showed the highest failure rate at 26% followed by Cotrimoxazole (an antibiotic used mostly for children) at 24%.

In 2001 it was estimated there were 2,800 illegal medicine sellers in Cambodia and 1000 unregistered medicines on the market. In the Lao People's Democratic Republic 2,100 illegal drug sellers are said to exist.

With more complex combination medicines now being recommended for drug-resistant malaria, there is a strong possibility that more substandard and counterfeit medicines will enter the market in malaria-endemic countries. Even in terms of older, more traditional antimalarials, the quality of the medicines is often poor.

A recent WHO survey of the quality of antimalarials in seven African countries (samples from Gabon, Ghana, Kenya, Mali, Mozambique, Sudan, and Zimbabwe) revealed that between 20% and 90% of the products failed quality testing. The antimalarials in question were chloroquine-based syrup and tablets, whose failure rate ranged from 23% to 38%; and sulphadoxine/pyrimethamine tablets, up to 90 % of which were found to be below standard. The medicines were a mixture of locally produced and imported products.

The reason why many of the antimaterials tested were substandard seems to stem from pervasive poverty. Poorly equipped laboratories, under-funded regulatory authorities, and poor handling and manufacturing practices mostly contributed to the results of the tests.

"Many tools exist to improve medicines' quality control and supply systems," explains Dr Vladimir Lepakhin, Head of Health Technology and Pharmaceuticals at WHO. "The problem is one of resources. Most of the countries with the lowest quality pharmaceuticals are also the ones with the highest disease burden and the poorest economies."

The findings of the report have provided a basis from which to address potential problems in the transition to the combination artesimin-based medicines for drug-resistant malaria and have given impetus to the fight against poor quality and counterfeit medicines in Africa.WHO is now running a series of training workshops in several African countries assisting manufacturers to upgrade their standards, and regulatory authorities (the national bodies meant to assure the quality and safety of medicines) to improve their practices in the screening and testing of local and imported products.

WMA Secretary General

From the Secretary General's Desk, May 2004

In political circles, the term **VISIBILITY** means a great deal. If a politician or organization has visibility, it has a better chance of convincing the electorate or general public of new directions or policies which should be followed, or the importance of maintaining a current position. Translated into our world of health care, the World Medical Association (WMA) can only act effectively as a strong advocate for the profession and the patients it serves, if it is **VISIBLE** on the global stage of leadership in health care. The question is therefore how visible the WMA is today, particularly in relation to its collaboration with the World Health Organization (WHO) and its impact on the members of WHO (the governments of the world).

Currently, the global leadership in health care is represented by a curious mix of players, including governmental, intergovernmental, non-governmental, and private groups, as well as some public-private partnerships. Because these groups have to get their message communicated and heard in a globalizing and highly information-driven world, there is tremendous competition to be the one to actually set or influence the

global health agenda. This battle often takes place during the WHO's annual meeting, the World Health Assembly (WHA), which happened to follow the WMA Council meeting in May 2004. During the WHA, governmental delegations from all countries of the world gather to discuss and set policy. As with all political meetings, the most important actions and political deal-making often take place in the corridors. It is therefore understandable that one would find in these corridors representatives of health professions' associations, non-governmental organisations and private industry, all trying to influence the decision-makers in a way which would be of benefit to the groups they represent. One of the most effective health professional groups in terms of lobbying has been the International Council of Nurses (ICN). During the WHA, they have a team advocating on behalf of nursing and make several interventions on matters which might have an impact on nursing and its future. Reflecting on how the WMA has performed in this regard, one must unfortunately concede that until the year 1999, the WMA voice had been largely absent. In fact, for several years, the WMA was not even in official relations with WHO.

Fortunately, this was rectified in 1996 when official relations were re-established. However, even after the "re-unification", it was distressing to find at that time a quite palpable "anti-physician" sentiment in WHO. In response to this undesirable situation, and in an effort to make the WMA more visible, the WMA leadership established a clear strategy in 1998 to improve relations with WHO and other international stakeholders. Almost immediately, the strategy bore fruit. In 1999, the WMA was requested by WHO to chair a planning committee of all the health professional associations for the development of a global program supporting World No Tobacco Day 1999. Subsequently, relations have been greatly strengthened, with many tangible results to confirm this increased visibility and political effectiveness, as for example:

- the WMA participated in all the negotiations and debates leading up to the adoption of the Framework Convention on Tobacco Control;
- the inclusion of the WMA in the WHO Global Alert and Response Network to combat communicable diseases. This has been updated to deal more effectively with new epidemics such as SARS;
- the development of policy on safe injections, with the Safe Injection Global Network (SIGN);
- the development of policy on "Violence and Health", and participation in the WHO launch of this project;
- the management of human resources for health.

Another important part of the WMA's "visibility" strategy was to encourage its members to work to become regular advisers to the governmental delegations participating in the World Health Assembly. In this regard, the May 2004 event had unprecedented levels of visibility for the WMA:

- 9 Governmental delegations to the WHA included representatives from the WMA leadership;
- 10 members of Council stayed on to attend part of the WHA;
- during the WHA, several interventions were made on behalf of the WMA;
- the WMA arranged a leadership symposium, in partnership with the International Council of Nurses and the International Pharmaceutical Federation, which was attended by the Councils of the three groups and WHO. This historic event was sponsored, in part, by WHO (another first) and the WHO Director-General was the keynote speaker;
- the WMA had two further receptions for Ministers of Health during the Assembly, each time drawing more than 40 Ministers of Health with their delegations. At one of the receptions, the WMA chose the theme of HIV/ AIDS, and it was remarkable that the three most prominent groups involved in this area all accepted invitations to speak – the Executive Director of UNAIDS, Dr. Peter Piot, the WHO Assistant Director-General, Dr. Jack Chow, and the Chair of the Global Fund to Fight AIDS, Tuberculosis and Malaria, Secretary Tommy Thompson of the USA.

Quite a remarkable turnaround in relations and visibility! In fact, it can be argued that the WMA has never been more **VISIBLE** on both the WHO and international stage of health leadership than it has been over the last month. This has required tremendous time and effort from all the leadership and staff of the WMA, but for a cause well worth it – our profession and our patients.

Needless to say, this was only the introduction to greater visibility and effectiveness in a never-ending quest for relevance and influence. In fact, Churchill's words ring true when we reflect on our **"visibility"** strategy and its first fruits:

"This was neither the beginning nor the end, rather, it was the end of the beginning."

Regional & NMA News

BANGLADESH

The Bangladesh Medical Association, with the collaboration of the Ministry of health and Family Welfare, the Ministry of LGRD and Co-operation has launched a Health Sector Strengthening Programme for capacity building of doctors and other staff fighting Arsenicosis and published a Training Manual for Trainers on the Early Diagnosis and Management of Arsenicosis, a major public health problem in this country. Whilst referring to the first case of large scale health problems caused by naturally occurring arsenic being in Taiwan in 1968, to its existence in many other countries and heavy dependence on groundwater for public drinking water supply, it is stated that problems in groundwater from the alluvial and deltaic aquifers of Bangladesh represent the most serious occurrences identified globally. In one survey across the country, 46% of wells less than 150m deep exceeded the WHO guideline of 10 µg/l. Dr. M.A. Hadi, President of the Bangladesh Medical Association, writes:

"One of the most serious public health problems that we are facing in Bangladesh is Arsenicosis. The majority of our people are exposed to this health hazard and a large number are also suffering from complications."

GERMANY

At the 107th meeting of the Deutscher Ärztetag (Annual Meeting of the German Medical Association) in Bremen, adherence to the provisions of the Helsinki Declaration was reinserted into the professional Ethical Regulations. At this meeting Dame Cicely Saunders, the pioneer of palliative medicine, was honoured by the award of the Paracelsus Medal, the highest award which the German Medical profession can bestow. Due to Dame Cicely's indisposition, the presentation was made in the U.K. by the President of the Bundesärztekammer, Professor Jörg-Dietrich Hoppe.

EU Enlargement

The enlargement of the European Union to 25 Member States means that the EU will constitute almost half of the WHO European Region (51 Member States).

TB Resistance and Aids Threat Growing Throughout Europe

UN, World Bank and Global Fund call on European Ministers to scale up HIV prevention and treatment programmes

Dublin – AIDS is rapidly spreading in Eastern Europe and is on the rise again in Western Europe because integrated prevention and treatment programmes have not been sustained or do not exist. Countries in Eastern Europe, home to the fastest-growing epidemic in the world, will be in Europe's borders following the European Union's enlargement on 1 May 2004. The Baltic States, which will be part ot the EU, are also experiencing a rapid rise in HIV infections.

Leading UN agencies, the Global Fund to Fight AIDS, Tuberculosis and Malaria and the World Bank are calling on European Ministers to urgently take decisive action to prevent the further spread of AIDS across Europe and to treat those in need. They warn that young people and other groups, such as sex workers, men who have sex with men and injecting drug users, are particularly at risk of HIV infection. The agencies participated in a Ministerial Conference hosted by the Irish EU Presidency, "Breaking the barriers – Partnership to fight HIV/AIDS in Europe and Central Asia", in Dublin.

"Europe and Central Asia are the centre of the fastest-growing HIV epidemic in the world. There is no time to waste – European Ministers must urgently scale up and roll out effective HIV prevention and treatment programmes," said Dr Peter Piot, UNAIDS Executive Director. "Given that the EU will form the biggest trading bloc in the world, covering more than 500 million people, it is in the EU's best interest to prevent the AIDS epidemic from crippling Europe's social and economic development."

Although most people in Western Europe now have access to free treatment through national health systems, many governments have not focused as much on prevention as they did in the 1990s. Infection rates are once again on the increase. Integrated prevention and treatment programmes are also urgently needed to ensure that life-prolonging treatment is not seen as a cure and to ensure that people living with HIV/AIDS continue to protect themselves and their partners.

Over 1.5 million people are living with HIV in Eastern Europe and Central Asia, compared to only 30,000 in 1995. Young people, who make up 40% of the population in the region, account for the majority of HIV infections among injecting drug users. A large number of them also engage in unsafe sex, increasing the risk of HIV. There is also evidence that people are having sex at a much younger age without protection. The percentage of people reporting premarital sexual relations more than doubled between 1993 and 1999, from 9% to 22%. Only 10% of girls in Tajikistan have ever heard of HIV/AIDS.

"Schools are the best defence against HIV infection," said Carol Bellamy, Executive Director of UNICEF. "They offer the best mechanism to deliver HIV prevention information, as well as the long-term educational and social skills that protect against infection. With knowledge so critical in the fight against HIV/AIDS, the best defence against the epidemic is keeping vulnerable young people, especially girls, in school."

In Eastern Europe and Central Asia, only 7000 people receive antiretroviral therapy for HIV, which is 9% of those in need in the region. For many, the treatment is too expensive or simply not available. To address this imbalance, the World Health Organization and UNAIDS have launched an ambitious challenge to get three million people on antiretrovirals by 2005 in developing countries and emerging economies. Dr LEE Jong-wook, WHO Director-General, said: "Treatment saves lives. Without treatment, the millions of people living with HIV will die prematurely. Prevention must go hand in hand with treatment. Europe cannot divide over the issue of AIDS treatment, and only provide treatment in the richer countries. Treatment should be a right for all, including for sex workers and injecting drug users."

In many countries of Western Europe, there are increasing rates of sexually transmitted infections, indicating resurgence in unsafe sex, primarily among young heterosexuals. In 2003 alone, between 30,000 and 40,000 people became infected with HIV, raising the number of people living with HIV to between 520,000 and 680,000. "The enlarged EU and its neighbours could rapidly be faced with a more vigorous phase of the epidemic unless political leaders transform their verbal commitments into concrete action on the ground," said Lars Kallings, the UN Secretary-General's Special Envoy for HIV/AIDS in Eastern Europe, speaking at the conference.

"Data from the region unambigously points to the socio-economic and governance dimensions of the epidemic. Members of at-risk groups are often subject to social exclusion, poverty, stigmatisation, or incarceration – factors which actually heighten the spread of the disease," said Kalman Mizsei, Assistant UNDP Administrator and Regional Director for Europe and the CIS.

In addition to increased AIDS funding from national governments, the World Bank and the European Union, the Global Fund to Fight AIDS, Tuberculosis and Malaria has approved over US$ 400 million in funding over five years for 22 programmes in 16 countries in Eastern Europe and Central Asia. Most of these funds are earmarked for HIV prevention and treatment programmes, along with programmes to control tuberculosis, the biggest killer of people living with HIV. Dr Richard Feachem, Executive Director of the Global Fund, said: "Swift implementation of programmes is possible, as our experience in Estonia has shown, moving from grant signing to first disbursement to implementation of targeted prevention and treatment programmes in just 12 weeks. Urgent action is needed throughout the region to turn the tide of the disease."

"Effective HIV/AIDS prevention and care programmes will require that funding from all sources increase to about US$ 1.5 billion by 2007. But money alone is not the issue. It is crucial to improve the information base for programmes, to support what works against HIV/AIDS, and to break down the policy and social barriers to effective actions across the region," said Shigeo Katsu, World Bank Regional Vice President for Europe and Central Asia.

Reviews

USEFUL BODIES

Humans in the service of medical science in the twentieth century

Jordan Goodman, Anthony McEllgott, and Lara Marks, Des.
Johns Hopkins University Press, 2003,
£31, pp. 217
ISBN 0 8018 7342 8

This multi-disciplinary volume is based on contributions to a workshop on Human Experimentation at the Wellcome Institute for the History of Medicine in London in 1998.

In a comprehensive introductory chapter "Making Human Bodies Useful", the editors set out their aim of presenting an historical review of medical experimentation in the 20th century based "not around the familiar doctor-patient or scientist-subject axis, … but on the role of the state as actor, legitimator and provider." They aver that "the concept of *usefulness* is the point of contact between human experimentation, knowledge, and the state. "With reference to the "horrible uniqueness" of medical experimentation in Nazi Germany and the consequential Nuremberg Code, they claim – with melancholy justification – that abusive practices flourished in medical practice in situations where the state was not so coercive as in Germany. They argue that 'medical science has become a constitutive force in the creation of a knowledge society', and they show that the hallowed concept of 'informed consent' which has dominated ethical discussion since Nuremberg is seriously flawed; even when it has been obtained, human experiments "may still violate the patient's autonomity". Examples abound of the experimental dilemma in which they are torn between the conflicting imperatives of obtaining information and preserving their ethical integrity. Subjects are too often unwitting if not unwilling.

The following seven chapters range widely throughout the world and the century, with reference to earlier ethical codes from Hippocrates, through Thomas Percival, to Claude Bernard, reviewing and discussing experiments on healthy individuals, groups of patients, military service personnel, and whole populations. Readers may be familiar with some of the examples, such as the investigations during and after the Second World War aimed at elaborating the complexities of viral hepatitis, and the exposure of 35,000 service personnel and 2,000 civilians to atomic blasts in Australia and on Christmas Island. Other examples may come as a shock, notably the germ warfare tests in the UK after World War II in which great swathes of the country were sprayed (without the knowledge or consent of the population, needless to say) with 'simulants' which post-hoc evaluation fortunately adjudged to be innocuous, and – at the other extreme of the spectrum of harm – the injection of comatose patients with uranium. The outstanding feature of every chapter is a cornucopia of notes (extended references and explanatory comments) which are a treasure for researchers. Conversely, an index was evidently considered redundant.

Although the authors address particularly the role of the state in influencing medical experimentation either directly as in the "euthanasia" of "lives unworthy of life" (lebensunwertes Leben) in pursuit of the demented "eugenic" policy of the Herrenvolk, or indirectly sponsoring selective experiments in its own interests as in the exposure of thousands of people to nuclear radiation, the compelling challenge of this book is to the medical experimenter. That challenge is to resist the temptation to rationalise, e.g. that the subjects are in a situation where it is assumed that they will become infected sooner or later, as in the case of the mentally retarded children in the Willowbrook State School on Staten Island who were administered infected material from patients with hepatitis. Arguably, it may be thought even less defensible to inflict potentially dangerous and traumatic experiments on "useless" patients suffering from, eg. an uncurable brain tumour or neurosyphilis, on the pretext that they can be rendered useful to medical science and its future beneficiaries.

Ultimately the challenge is to the integrity and the conscience of researchers and their ability to resist the blandishments of finance, fame and fortune.

A. W. Macara

The Confinement of the Insane: International Perspectives 1800-1965

Roy Porter and David Wright,Eds.,
Cambridge University Press 2003,
£59, pp 371, ISBN 0521802067, Hardback

Samuel Johnson defined 'to enlighten' as 'to illuminate, to supply with light, to instruct, to furnish with increase of knowledge, to cheer, to exhilarate, to gladden, to supply with sight, to quicken the faculty of vision'. So we are informed in Roy Porter's brilliant book 'Enlightenment' (2000). In all senses of the word, Roy Porter himself enlightened the history of medicine, including psychiatry, in his own writings and in his exhilarating teaching of a host of gladdened and quickened students at the Wellcome Institute for the History of Medicine. Many of these have contributed to this volume, which is dedicated to him. He died – much too early – in March 2002, but not before contributing a characteristically lively and generous Introduction, summarising all the contributions and reviewing some of the conflicting interpretations of the chequered history of psychiatry. He relished the clash of views, and the opportunies to challenge all of them in turn, through careful research.

The sub-title 'International Perspectives' is fully justified, as every continent gets attention – Switzerland, Germany, France, England and Ireland in Europe; Nigeria and the Cape (Robben Island) in Africa; Victoria in Australia; Canada, USA, Mexico and Argentina in America; India and Japan in Asia. All the contributions make interesting reading.

The dates are not so precise as suggested, a few accounts beginning before 1800 and several going up to the end of the last century. The print is clear, but some of the figures, a murky patchwork of grey stippling, are rather difficult to make out.

A simplistic narrative of British psychiatry begins in the late 18th century, when some leading local benefactors decided to build handsome hospitals, each with a classical portico, which would care for unfortunate lunatics in a humane and up-to-date fashion and return them to their homes or other accommodation in due course. But these patients did not all recover, nor did they die, but survived as an increasing burden – a space-occupying lesion which required the gradual enlargement of the hospital. The result was a degraded and deteriorating environment, with the portico dwarfed by the ramparts of later building, and the disillusionment of staff patients and their families; and a fall in income. One of the founding notions had been that the better-off patients would pay for better accommodation. But these now stayed away, and their contributions, always smaller than expected, became insignificant. The occasional scandal led to management changes and some transient improvement. Meanwhile, all this did not deter a considerable investment of public money in the construction and staffing of local mental hospitals throughout the 19th century.

In his lifetime, Roy Porter encouraged a different approach of 'history from below', based on, the people and processes involved in the system and their networks. There are several examples of this approach in the book, as well as others on more traditional lines.

For instance, in Argentina, a country with a stormy political history, the first asylum to be opened, in an old convent in Buenos Aires in 1854, admitted only women. The men's asylum opened 9 years later. There were only 200 beds in each, to serve not just the capital but the whole country, whose welfare system was focussed on the needs of working people in various industries rather than on the indigent poor. The Ministry in charge was that of 'Foreign Relations and Religion' (the Health Ministry only took responsibilty reluctantly, and under intense pressure, in 1947). Both hospitals were soon in trouble with, among other things, a serious shortage of nurses. The women's hospital had a tradition of recruiting its staff from female immigrants as they arrived at the dockside. (In Ontario, by contrast, recently arrived and homeless female immigrants, mostly from Ireland, made a considerable contribution to the hospital – as patients.) Argentina passed its first mental health act in 1983.

In Mexico (1910 - 1930), the opening of the General Insane Asylum in 1910, in a village just outside the city boundary, had been preceded by nearly 20 years of planning and consultation, including advice from Baron Haussmann, the transformer of Paris. (The administrative building had an imposing classical facade.) The paying patients had bedrooms and the others were housed in wards. This hospital could accommodate 1,330 patients – some 500 more than the two which had preceded it. But the social upheavals of the long Mexican revolution led to greatly increased demands and shortage of funds. The hospital was destitute by 1920, starved of food, shelter and staff. Yet it remained open, serving particularly the homeless and indigent, and providing 24 hours' shelter for drying out a drunken man, or 24 years for someone with a chronic mental illness. Cristina Rivera-Garza emphasises the important role which the families played in initiating admissions – those on a State Order as well as 'voluntary' – and in remaining in touch with the patients and liaising with staff concerning their progress.

Continuing the view from below, Patricia Prestwich reports on a development in Paris, where in 1876 the psychiatrists at St Anne, the city asylum, negotiated a system of 'voluntary admisssion', in which the patient was admitted at the request of the family, who retained control of the decision for discharge. The current police proceedings had been fiercely criticised as heavy-handed and intimidating. The psychiatrists wanted more acute and curable patients and a better image – and also a financial contribution from the families, some of whom paid for separate rooms and better food. The new system was a success, and was extended to some other asylums. Dangerousness was not a neces-

sary criterion for admisssion, as it was for the 'official' patients, so people could be admitted before they had frightened their families irrevocably. Nearly 40% were admitted by their spouses, husbands and wives in equal proportions. Compared with the 'official' patients, they were more likely to be released – too early, the psychiatrists complained – but they were transferred to other asylums less frequently, and after much longer stays, often more than two years, at St Anne. In general, the relatives were not waiting for a complete recovery but for a tolerable level of behaviour, with a capacity to provide support either at work or at household tasks. The prolonged absence of a wife could result in children being sent away to relatives and the husband left to fend for himself. Although in hospital, the patient retained the important support of remaining involved in his or her rôle in the family.

The scenario in Paris in the late 19th century may seem fairly familiar to most readers of the World Medical Journal. But Akihito Suzuki's contribution on 'The state, the family and the insane in Japan 1900 - 1945' takes them to a different society, where home care meant confinement in a cage, in or near the family house, and where lunatics, beggars (and also Koreans, socialists and those suffering from infectious diseases) were 'swept' off the streets into some sort of confinement on the days preceding and during a Royal visit or ceremony – a practice which also occurred in the Soviet Union on certain public holidays.

The responsibility for confining lunatics, generally regarded as dangerous, rested with the family. In one village during the late 19th century, when a lunatic son escaped from his father's house, killing two villagers and then himself, half of the father's property was confiscated and he was expelled from his village. Such family confinement could be and was abused. The first Mental Patients' Custody Act was passed by the Westernising regime in 1900. This codified home confinement and criminalised its unjust use. A 'competent custodian' would be appointed. and the imposition of custody and release from it required the approval of a 'local senior administrator. In fact all real responsibility rested locally, with the family and the village chief. No central authority was involved. Hospital confinement was also legal, but at that time there was only one hospital, in Tokyo.

The pressure for expansion was increased by the Mental Hospitals Act of 1919. At this date, while England and Wales with a population of 35 million had 100,000 hospital beds, Japan with a population of 55 million had 4,000, of which only 450 were in the single public hospital in Tokyo. The rest were in 57 private hospitals. By 1940 there were 7 public and 160 private hospitals with a median length of stay of 717 days and 44 days respectively. The number of home custody cases continued to grow slowly until the late 1930s and remained a crucial part of psychiatric provision; but the hospitalisation rate grew much faster – mainly in the private sector which looked after a considerable number of long-stay patients who brought in a stable income from the public purse. At the same time they were competing (successfully) for the acute patients and touting for trade at the entrance to the Tokyo Metropolitan Asylum, where the private Tokyo Brain Asylum advertised an 'inpatients' information office' on a large billboard. Suzuki comments that 'the mutual stimulation between the public and private sector seems to have been the main engine behind the increased institutionalisation of the insane'. (He might have added 'and remains so today, in Japan.')

One question which many contributors address is 'Did the Great Confinement as proclaimed by Michel Foucault in his "Madness and Civilisation" really exist?' The answer seems to be No, in so far as the population of those being admitted was quite representative of the population as a whole, with rather more 'unsupported' groups – single men and the poor – but not specifically deviant. And the numbers 'confined', at least at first, were quite small, not great in epidemiological terms; and at least 50% would be discharged. But there was a 'great accumulation' which required expansion, and made the hospitals look and feel like factories or warehouses. Elaine Murphy in her chapter on 'Insanity in England 1800-1870' makes the important point that in London large asylums replaced the large network of private asylums, pauper houses and farms which provided the refuge for 'dull-witted, incompetent and dependent paupers' which was administered by the Poor Law Commissioners. The attraction of the new asylums was their lower charges: eight shillings and ninepence a week at Hanwell compared to eleven shillings for the private asylums. However, Hanwell's low cost depended on its high occupancy. Foucault's insistence on the Great Confinement may be wide of the mark, but Andrew Scull's economic interpretation remains closer to the truth. Lord Shaftesbury, the reforming Chairman of the Lunacy Commisssion, would have supported it. In 1859 he commented that:

When I look into the whole matter I see that the principle of profit vitiates the whole thing. It is at the bottom of all these movements that we are obliged to counteract by complicated legislation, and if we could but remove that principle of making a profit we should confer an inestimable blessing upon the middle classes, getting rid of half the legislation and securing an admirable, sound and efficient system of treatment of lunacy.

Doctors are taught that 'taking a careful history' is an essential skill for clinical competence. In psychiatry this is of particular importance. Over the past ten years there has been a huge expansion of studies of its history. This volume is one of them; and its world perspective makes it particularly helpful in diagnosing and treating our current local problems. lt is indeed enlightening.

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Web-based course on Human Rights for Prison Doctors

The web-based accredited course for Prison Doctors on Human Rights and Ethical Dilemmas announced in the World Medical Journal (WMJ 50 (1), 27) has been finalised and is now accessible via the WMA website at www.wma.net. No course fee is charged.

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